UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation,	)	MD 15-02641-PHX-DGC
Lisa Hyde and Mark Hyde, a married couple,	)	Phoenix, Arizona **October 3, 2018**
Plaintiffs,	)	
v.	)	CV 16-00893-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation, and Bard Peripheral Vascular, an Arizona corporation,	)	
Defendants.	)	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 12 - P.M. SESSION

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Proceedings Reported by Stenographic Court Reporter
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I N D E X

P R O C E E D I N G S

(Proceedings resumed at 12:56 p.m.)

(Jury not present.)

THE COURT: All right, everybody. Let me tell you what I found in my lunchtime reading.

I reviewed every one of the cases cited in the note, the comment after the jury instruction. None of them was on point, but there were some that are helpful. One of the cases was the *Fouse*, F-O-U-S-E, case. I won't give the cites since they're all in the comment.

It was a case where the plaintiff introduced evidence of medical and hospital expenses of $5,400 and the jury awarded $1,750. And the Court of Appeals of Wisconsin said that the jury's award had no rational relationship to the evidence, and therefore set aside the verdict because they couldn't find a basis the jury used to reduce the amount awarded. This suggests that a jury award must be tied to the evidence and the jury just can't freelance and arrive at its own value.

A similar case was the *Nimlos*, N-I-M-L-O-S, case, which was a Wisconsin case, where the jury arrived at what the Court viewed as a high value for the cost of medical care, and concluded that the value awarded by the jury wasn't closely enough related to the evidence to have an evidentiary basis and so set aside the award; again, suggesting a jury just can't pick its own number for damages.

There was a case -- well, there's language in the *Green* case, which is a Wisconsin case, that says where a medical bill may relate to two separate maladies, one having nothing to do with the plaintiff's claim, plaintiff must prove which charges relate to the injury caused by the defendant.

So there has to be a connection between an amount of a medical cost and a particular injury. And in this case, I don't believe there's a connection between future medical monitoring costs and past medical expenses.

The most relevant case, it's not directly on point, but the most relevant case, however, is not cited. I should say the most relevant one we found is not cited in the instruction comments, but it's the *Reyes* case, R-E-Y-E-S, that was actually cited by the parties on a different proposition, actually, for the point that the possibility of future medical expenses is not sufficient.

And it has this discussion talking about future medical expenses, but I believe it is relevant to the issue in front of me. And this is a Wisconsin Court of Appeals decision from 1998.

It says: The amount of damages to award is a matter resting largely within the jury's discretion, but the jury's discretion to award damages is not without limits. Credible evidence in the record must support the amount of damages awarded or it will be deemed excessive.

Reyes acknowledges that there is no direct evidence in the record supporting an award of $39,820 for the cost of removing the eye if it becomes shrunken. This is a future medical cost discussion.

Nonetheless, he argues that the award was not speculative. He contends that the cost of this type of medical procedure is generally known to the public, though he does not explain how that is so. Also, Reyes claims that the jury could accurately calculate any future medical costs based on the testimony it heard regarding the medical costs Reyes incurred trying to save the eye. Again, Reyes does not inform us how the jury could calculate, in quotes, in this instance.

We are not persuaded by Reyes's response. An award of future medical expenses will not be upheld if it is unsupported in the record by expert medical testimony -- that's clearly not required for past damages -- but then it says: Reyes's concession that no evidence in the record directly supports an award of $39,820 defeats any argument that the award was not speculative.

With no evidence in the record to support the award, we can only conclude that the jury created a figure. We, therefore, reduce the award of future medical expenses to an amount that it said was supported by credible evidence. That was an amount of $10,000.

So this tells me that there has to be some evidence in

the record from which the jury can calculate an amount, that the jury simply can't look to unrelated future expenses in calculating the amount of past expenses.

And as I said before lunch, in this case, I don't believe there is any direct evidence from which the jury can calculate the amount of past expenses. It's not enough for the jury to just freelance and do it on its own, nor, in my view, do the future medical expenses relate sufficiently to past medical expenses to support an award.

For that reason, I'm going to grant the Rule 50 motion on past medical expenses.

The change I propose to make to Instruction No. 17, I think, was handed to you. I have redlined the language I propose to delete from the fifth -- I'm sorry, sixth paragraph. And I'm interested in your comments on whether that's the right fix to the instruction in light of my ruling.

MR. ROGERS: Your Honor, I understand from the defense camp that we are okay with the language.

MR. GOLDENBERG: Your Honor, I am so sorry. I just got this handed to me. Can you just point out the area that you changed?

THE COURT: Yeah, it's the bottom -- do you have the redlined version? It's the smaller type.

MR. GOLDENBERG: I don't have the redlined version.

THE COURT: Traci, take this down, if you would.

You'll see what I'm taking out in the last paragraph on the first page.

MR. GOLDENBERG: I think that's fine, Your Honor.

THE COURT: All right. So I'll give the instruction in that form.

Okay. We'll bring in the jury and instruct them and then go into arguments.

Traci, why don't you go ahead and get them.

Mr. Lopez, are you doing the closing?

MR. LOPEZ: Yes, I am, Your Honor.

THE COURT: How much time do you plan?

MR. LOPEZ: I'm going to keep it at under an hour.

THE COURT: Do you want me to do anything to prompt you on time or do you want to take care of it?

MR. LOPEZ: At 35 and 45.

THE COURT: 35 and 45? Okay. I'll give you a prompt then.

MR. LOPEZ: Thank you.

MS. REED ZAIC: Your Honor, we have one more matter. I was under the impression the defendants were going to bring it up.

THE COURT: Hold on just a minute.

MS. REED ZAIC: It's a very quick housekeeping matter.

Document 12735 was filed by the defendants. It was an objection to evidence that has not come into evidence. It was

the complaint summary that came in in Jones, which was not entered into evidence here.

And rather than me having to make a filing because they've not corrected it, I just wanted to put it on the record that that is a clarification that's being -- that part of the objection is being withdrawn.

MS. HELM: Your Honor, we've agreed -- now that the evidence is closed and it's not in, we've agreed to make that. I'll file an amended objection. We simply -- at your request, we memorialized our objection in writing. I'll file an amended objection now that the evidence is complete.

THE COURT: That's fine.

Who's doing the closing for defendants?

MR. ROGERS: I will be, Your Honor.

THE COURT: And how much time do you expect it to be?

MR. ROGERS: I would expect it's going to be about an hour and 15.

THE COURT: Do you want me to give you any prompts on the time?

MR. ROGERS: Sure. If I hit an hour --

THE COURT: I don't -- it's not that I want to do it.

MR. ROGERS: No, I understand, Your Honor.

THE COURT: I'm just trying to be helpful if you think it would.

MR. ROGERS: No, and I would appreciate that. If we

get to an hour, if you would let me know, that would be great.

THE COURT: Okay. I'll do that.

MR. ROGERS: Thank you.

MR. LOPEZ: And, Your Honor, Mr. O'Connor's going to do rebuttal. Is that okay?

THE COURT: Yeah. That's all right.

(Jury present.)

THE COURT: Please be seated.

All right, ladies and gentlemen. I am now going to give you the jury instructions that will apply in this case.

Counsel, as I read these, if you could follow along, since we've been doing some adjusting, just so that you catch any errors if I make them.

Members of the jury, now that you have heard all of the evidence, it is my duty to instruct you on the law that applies to this case.

A copy of these instructions will be sent to the jury room for you to consult during your deliberations.

It is your duty to find the facts from all the evidence in the case. To those facts, you will apply the law as I give it to you. You must follow the law as I give it to you, whether you agree with it or not, and you must not be influenced by any personal likes or dislikes, opinions, prejudices, or sympathy. That means that you must decide the case solely on the evidence before you. You will recall that

you took an oath to do so.

Please do not read into these instructions or anything that I may say or do or have said or done as indicating that I have an opinion regarding the evidence or what your verdict should be.

Although there are two defendants in this case, C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., you should decide the case as to the two defendants jointly. As a result, in these instructions and in the verdict form, we will refer to defendants collectively as "Bard." Unless otherwise stated, the instructions apply to both Bard and the plaintiffs.

The evidence that you are to consider in deciding what the facts are consists of the sworn testimony of the witnesses; the exhibits that are admitted into evidence; any facts to which the lawyers have agreed; and any facts that I have instructed you to accept as proved.

In reaching your verdict, you may consider only the testimony of the witnesses, the exhibits received into evidence, and the facts to which the parties have agreed or which I have instructed you to accept.

Certain things are not evidence, and you must not consider them in deciding what the facts are. I will list them for you.

First, arguments and statements by lawyers are not evidence. The lawyers are not witnesses. What they have said

in their opening statements, may say in their closing arguments, and at other times, is intended to help you interpret the evidence, but it is not evidence. If the facts as you remember them differ from the way the lawyers have stated them, your memory of the facts controls.

Second, questions and objections by lawyers are not evidence. Attorneys have a duty to their clients to object when they believe a question is improper under the rules of evidence. You should not be influenced by the objections or by my rulings on them.

Third, testimony that is excluded or stricken or that you were instructed to disregard is not evidence and must not be considered. In addition, some evidence is received only for a limited purpose -- only for a limited purpose. When I instruct you to consider certain evidence only for a limited purpose, you must do so, and you may not consider that evidence for any other purpose.

Fourth, anything that you may have seen or heard when the court was not in session is not evidence. You are to decide the case solely on the evidence received during the trial.

Some exhibits admitted into evidence have been partially redacted, which means that certain contents of the exhibits have been blacked out or whited out. The parties and I have redacted information that is not properly admitted as

evidence. You may give the unredacted information in any exhibit whatever weight you choose, but you must disregard the redacted information and must not speculate about what it might say.

You have heard testimony from a number of witnesses who testified to opinions and the reasons for their opinions. This opinion testimony is allowed because of the education or experience of those witnesses.

Such opinion testimony should be judged like any other testimony. You may accept it or reject it and give it as much weight as you think it deserves, considering the witness's education and experience, the reasons given for the opinion, and all the other evidence in the case.

Federal law prohibits current FDA employees from testifying in court regarding any function of the FDA, and prohibits current and former FDA employees from testifying about information acquired in the discharge of their official duties without authorization from the Commissioner of the FDA. As a result, neither side in this case was able to present testimony from current FDA employees or former FDA employees regarding the discharge of their duties related to this case.

Each side has presented expert witnesses to testify about FDA procedures and the 510(k) process in this case, but this testimony was based on the expertise of these witnesses and work they did after being retained as experts in this

litigation.

Certain charts and summaries not admitted into evidence have been shown to you in order to help explain the evidence in the case. These have been referred to as demonstrative exhibits. The demonstrative exhibits are only as good as the underlying evidence that supports them. You should, therefore, give them only such weight as you think the underlying evidence deserves.

All parties are equal before the law, and a corporation is entitled to the same fair and conscientious consideration by you as any party.

Under the law, a corporation is considered to be a person. It can only act through its employees, agents, directors, or officers. Therefore, a corporation is responsible for the acts of its employees, agents, directors, and officers performed within the scope of authority.

Plaintiff Lisa Hyde asserts two claims against Bard: strict liability based on design defect, and negligent design. Plaintiff Mark Hyde asserts a derivative claim for loss of consortium. I will instruct you on the law that applies to each of these claims. You should consider each claim separately.

Plaintiff seeks compensatory damages, which are damages to compensate them for their alleged injuries. Plaintiffs also seek punitive damages to punish Bard for its

allegedly wrongful conduct. I will instruct you on the law that applies to compensatory and punitive damages.

Before I give you instructions about plaintiffs' specific claims, I will give you a few instructions about the verdict form you will complete after your deliberations and the burden of proof for the claims.

I'll talk about the burden of proof now and explain the verdict form in a minute.

The verdict form requires you to state whether you find for plaintiffs or Bard on each claim. For each claim, the burden is on plaintiffs to satisfy you by the greater weight of the credible evidence, to a reasonable certainty, that you should find for plaintiffs. If you find that plaintiffs have met this burden of proof on any claim, you should find for plaintiffs on that claim. If you find that plaintiffs have not met this burden of proof on any claim, you should find for Bard on that claim.

"Credible evidence" means evidence you believe in light of reason and common sense.

The "greater weight" of the credible evidence means that the evidence in favor of a finding for a party has more convincing power than the evidence opposed to it.

"Reasonable certainty" means that you are persuaded based upon a rational consideration of the evidence. Absolute certainty is not required, but a guess is not enough to meet

the burden of proof.

Mrs. Hyde contends that Bard is strictly liable because of a design -- because of a defective design of the Bard IVC filter she received. To prove -- to prove the liability of Bard for the strict liability design defect claim, Mrs. Hyde must establish each of the following five elements:

First, the filter is defective because the foreseeable risk of harm posed by the filter's design could have been reduced or avoided by the adoption of a reasonable alternative design by Bard, and the omission of the alternative design renders the product not reasonably safe.

Second, the defective condition rendered the filter unreasonably dangerous to persons or property.

Third, the defective condition existed at the time the filter left the control of Bard.

Fourth, the filter reached the user or consumer without substantial change in the condition in which it was sold.

And, fifth, the defective condition was a cause of Mrs. Hyde's damages.

Mrs. Hyde may not recover on the strict liability design defect claim if the damages were caused by an inherent characteristic of the product that would be recognized by an ordinary person with ordinary knowledge common to the community that uses or consumes the product.

Mrs. Hyde also claims that Bard was negligent in the design of the Bard IVC filter she received.

A person is negligent when he or she fails to exercise ordinary care. A person is not using ordinary care if the person, without intending to do harm, does something or fails to do something that a --

Okay. That's all right.

(Brief pause in proceedings.)

THE COURT: How does that sound?

JURY MEMBER: Good.

THE COURT: All right. I'm going to start this instruction over.

Mrs. Hyde also claims that Bard was negligent in the design of the Bard IVC filter she received.

A person is negligent when he or she fails to exercise ordinary care. Ordinary care is the care which a reasonable person would use in similar circumstances. A person is not using ordinary care if the person, without intending to do harm, does something or fails to do something that a reasonable person would recognize as creating an unreasonable risk of injury or damage to a person or property.

It is the duty of a manufacturer to exercise ordinary care in the design of its product so as to render the product safe for its intended use and also safe for unintended uses which are reasonably foreseeable.

It is the further duty of the manufacturer, in the exercise of ordinary care, to make all reasonable and adequate tests and inspections of its product so as to guard against any defective condition which would render the product unsafe when used as it is intended to be used. A manufacturer is charged with knowledge of its own methods of designing its products and the defects in such methods, if any.

Failure of the manufacturer to perform any such duty constitutes negligence.

If you find that the Bard IVC filter was defectively or negligently designed, you must also decide whether the design caused injury to Mrs. Hyde. An injury may have more than one cause. The defective or negligent design caused an injury if it was a substantial factor in producing the injury. An injury may be caused by one cause or by the combination of multiple causes.

It is the duty of the Court to instruct you about the measure of damages. By instructing you on damages, I do not mean to suggest for which party your verdict should be rendered.

If you find for Mrs. Hyde on any claim, the verdict form will require you to find the amount of damages that will reasonably compensate her for her injuries or losses. In considering the amount to be awarded as damages, if any, the burden of proof rests on Mrs. Hyde to satisfy you by the

greater weight of the credible evidence, to a reasonable certainty, that she sustained damages with respect to the claim and the amount of the damages sustained.

As you have seen, or will see when you see the copy of the instructions, Instruction 12, which I have already given you, provides a further explanation of this burden of proof.

If you find for Mrs. Hyde on one or both of her claims, you must determine her compensatory damages. Your answer to this question should be the amount of money that will fairly and reasonably compensate Mrs. Hyde for the injuries she has suffered to date and is reasonably certain to suffer in the future as a result of the defective or negligent design of the Bard IVC filter.

Personal injuries include pain and suffering, which means any physical pain, worry, distress, embarrassment, and humiliation which Mrs. Hyde has suffered in the past and is reasonably certain to suffer in the future. You should consider the extent to which Mrs. Hyde's injuries have impaired and will impair her ability to enjoy the normal activities, pleasures, and benefits of life.

Also consider the nature of her injuries, the effect produced by her injuries in the past, and the effect the injuries are likely -- are reasonably certain to produce in the future, bearing in mind her age, prior mental and physical condition, and the probable duration of her life.

Determining damages for pain and suffering cannot always be made exactly or with mathematical precision. You should award as damages amounts which will fairly compensate Mrs. Hyde for her injuries.

Personal injuries can also include healthcare and treatment expenses. If you are satisfied that Mrs. Hyde will require healthcare and treatment expenses in the future for injuries sustained as a result of the negligent or defective design, include in your damages award the sum of money that will reasonably and necessarily be expended in the future for that care and treatment.

However, other than fear of future events, you should not award any damages for the cost of a defibrillator or any other medical costs or injuries associated with future cardiac arrhythmias.

The amount of damages is for you to determine from the evidence. You should not be affected by sympathy or resentment, nor should you make any deductions based on a doubt in your minds as to the liability of Bard.

What the attorneys ask for in their arguments is not a measure of damages. The opinions or conclusions of counsel as to what damages should be awarded should not influence you unless it is sustained by the evidence. Examine the evidence carefully and dispassionately and determine the amount of damages from the evidence in the case.

In determining the amount of damages for medical expenses incurred by Mrs. Hyde in the future, if any, you must determine the present worth in dollars of the future damages.

A lump sum of money received today may be worth more than the sum paid in installments over a period of months or years. This is because a sum received today can be invested and earn money at the current interest rates. By making a reduction for the earning powers of money, your answer will reflect the present value in dollars of an award of future damages.

This instruction, which asks you to reduce future damages to present value, does not apply to that portion of future damages which represent future pain and suffering.

Plaintiff Mark Hyde asserts a claim for loss of consortium. This claim is derivative of the strict liability design defect and negligent design claims asserted by plaintiff Lisa Hyde. You, therefore, may award loss of consortium damages to Mr. Hyde only if you find Bard liable to Mrs. Hyde on one or both of her claims.

"Consortium" involves the love and affection, the companionship and society, the privileges of sexual relations, the comfort, aid, advice, and solace, the rendering of material services, the right of support, and any other elements that normally arise in a close, intimate, and harmonious marriage relationship. A wrongful invasion, impairment, or deprivation

of any of these rights resulting from a disabling injury to a spouse is a legal loss and a basis for damages to the other spouse harmed or deprived.

In evaluating this claim, you should consider the nature, form, and quality of the relationship that existed between the spouses up to the time of the injury. Based on that relationship, determine what sum of money will represent fair and reasonable compensation for any loss of consortium that was sustained by Mr. Hyde as a result of the injury.

If you find that the loss will continue in the future, include an amount of damages for the period you are convinced it will continue to exist.

Compensation for loss of consortium, except as it relates to material services, is not measured by any rule of market value. Instead, it is measured on the basis of what you find is fair and reasonable compensation for the loss sustained by the deprived spouse. Compensation for material services is to be measured by what it would reasonably cost in the market for like services.

In determining future damages as a result of plaintiff's injuries or losses, you may consider the fact that at this time Mrs. Hyde is 54 years of age and has a life expectancy of 29.61 more years.

Testimony based on mortality tables -- that's where that number came from -- was received in evidence as an aid in

determining such expectancy. The evidence is not, however, conclusive or binding upon you as to Mrs. Hyde's actual or probable expectancy of life.

Mortality tables are based upon averages, and there is no certainty that any person will live the average duration of life rather than a longer or shorter period. To determine the probable length of life of Mrs. Hyde, you should consider all of the facts and circumstances established by the credible evidence bearing on that subject.

Does that work?

JURY MEMBER: Yes.

THE COURT: Did you hear the end of my last instruction?

JURY MEMBER: Possibly not the very last.

THE COURT: All right. I will read that instruction again.

JURY MEMBER: Thank you.

THE COURT: In determining future damages as a result of plaintiff's injuries or losses, you may consider the fact that at this time Mrs. Hyde is 54 years of age and has a life expectancy of 29.61 more years.

Testimony based on mortality tables was received in evidence as an aid in determining such expectancy. That evidence is not, however, conclusive or binding upon you as to Mrs. Hyde's actual or probable expectancy of life.

Mortality tables are based upon averages, and there is no certainty that any person will live the average duration of life rather than a longer or shorter period. To determine the probable length of life of Mrs. Hyde, you should consider all the facts and circumstances established by the credible evidence bearing upon that subject.

In determining the amount of compensatory damages, if any, you must not include in the award, or add to it, any sum to compensate plaintiffs for state or federal income taxes, since damages received as an award for personal injuries or loss of consortium are not subject to income taxes. You may not subtract from or exclude from your award of compensatory damages any amount because plaintiffs are not required to pay income taxes.

Punitive damages may be awarded, in addition to compensatory damages, if you find that Bard acted maliciously toward plaintiffs or in an intentional disregard of the rights of plaintiffs.

A person acts maliciously when the acts are the result of hatred, ill will, desire for revenge, or inflicted under circumstances where the insult or injury is intended.

A person acts in an intentional disregard of the rights of a plaintiff if the person acts with the purpose to disregard the plaintiff's rights, or is aware that his or her acts are substantially certain to result in the plaintiff's

rights being disregarded. Before you can find an intentional disregard of the rights of the plaintiff, you must be satisfied that the defendant's acts or a course of conduct was:

First, deliberate;

Second, an actual disregard of the plaintiff's right to safety, health, or life, a property right, or some other right; and

Third, sufficiently aggravated to warrant punishment by punitive damages.

A defendant's conduct giving rise to punitive damages need not be directed at the plaintiff seeking punitive damages. There is no requirement that the defendant intended to cause harm or injury to the plaintiff.

The purpose of punitive damages is to punish a wrongdoer or deter the wrongdoer and others from engaging in similar conduct in the future. Punitive damages are not awarded to compensate the plaintiff for any loss he or she has sustained.

A plaintiff is not entitled to punitive damages as a matter of right. Even if you find that the defendant acted maliciously or in an intentional disregard of the plaintiff's rights, you do not have to award punitive damages. Punitive damages may be awarded or withheld at your discretion.

Punitive damages may not be awarded to punish a defendant for harming others. Evidence of actual harm to

nonparties may help to show that the defendant's conduct that harmed the plaintiff also posed a substantial risk to the general public and so was particularly reprehensible. However, punitive damages may not be used to punish the defendant directly for harm to these nonparties.

The burden for punitive damages rests on plaintiffs. The burden is to convince you by evidence that is clear, satisfactory, and convincing, to a reasonable certainty, that an award -- that an award of punitive damages is warranted.

Clear, satisfactory, and convincing evidence is evidence which, when weighed against that opposed to it, clearly has more convincing power. It is evidence which satisfies and convinces you that punitive damages should be awarded because of its greater weight and clear convincing power.

This burden of proof is also known as the "middle burden." The evidence required to meet this burden of proof must be more convincing than merely the greater weight of the credible evidence but may be less than proof beyond a reasonable doubt.

In the verdict form, you will be asked to specify whether plaintiffs are entitled to recover punitive damages, but you will not be asked to determine an amount of punitive damages. If you decide the plaintiffs should be awarded punitive damages, then you will receive some additional brief

instructions, evidence, and argument before setting the amount.

There can be no recovery of punitive damages in this case unless there is first a recovery by plaintiffs of compensatory damages.

Before you begin your deliberations, please elect one member of the jury as your presiding juror. The presiding juror will preside over the deliberations and serve as the spokesperson for the jury in court.

You shall diligently strive to reach agreement with all of the other jurors if you can do so. Your verdict must be unanimous.

Each of you must decide the case for yourself, but you should do so only after you have considered all of the evidence, discussed it fully with the other jurors, and listened to their views.

It is important that you attempt to reach a unanimous verdict, but, of course, only if each of you can do so after having made your own conscientious decision. Do not be unwilling to change your opinion if the discussion persuades you that you should, but do not come to a decision simply because other jurors think it is right or change an honest belief about the weight and effect of the evidence simply to reach a verdict.

Because you must base your verdict only on the evidence received in the case and on these instructions, I

remind you that you must not be exposed to any other information about the case or to the issues it involves. Except for discussing the case with your fellow jurors during your deliberations, I remind you again:

Do not communicate with anyone in any way, and do not let anyone else communicate with you in any way about the merits of the case or anything to do with it. This includes discussing the case in person, in writing, by phone or electronic means, via e-mail, text messaging, or any internet chat room, blog, website, or application, including, but not limited to, Facebook, YouTube, Twitter, Instagram, LinkedIn, Snapchat, or any other form of social media.

This applies to communicating with your family members, your employer, the media or press, and the people involved in the trial. If you are asked or approached in any way about your jury service or anything about this case, you must respond that you have been ordered not to discuss the matter and to report the contact to the Court.

Do not read, watch, or listen to any news or media accounts or commentary about the case or anything to do with it; do not do any research, such as consulting dictionaries, searching the internet, or using other reference materials; and do not make any investigation or in any other way try to learn about the case on your own.

Do not visit or view any place discussed in this case,

the law, or the people involved -- including the parties, the witnesses, or the lawyers -- until you have been excused as jurors. If you happen to read or hear anything touching on this case in the media, turn away and report it to me as soon as possible.

As I've explained before, these rules protect each party's right to have this case decided only on evidence that has been presented here in court. Witnesses here in court take an oath to tell the truth, and the accuracy of their testimony is tested through the trial process. If you do any research or investigation outside the courtroom or gain any information through improper communications, then your verdict may be influenced by inaccurate, incomplete, or misleading information that has not been tested by the trial process.

Each of the parties is entitled to a fair trial by an impartial jury, and if you decide the case based on information not presented in court, you will have denied the parties a fair trial. Remember that you have taken an oath to follow the rules, and it is very important that you follow these rules.

A juror who violates these restrictions jeopardizes the fairness of these proceedings, and a mistrial could result that would require the entire trial process to start over. If any of you is exposed to any outside information, please notify me immediately.

The exhibits that are in evidence are capable of being

displayed electronically and will be provided to you in that form, and you will be able to review them in the jury room. The machine that was sitting here earlier, the big screen with the computer, has been moved back to the jury room. Maybe it's in the hall, but it will be placed in the jury room.

A computer, projector, printer, and accessory equipment will be able available to you in the jury room.

Actually, I don't know if we have a printer.

THE COURTROOM DEPUTY: No printer.

THE COURT: I don't think we do. That's in the standard instruction, but there will be a computer and that big screen where you can view it.

A court technician, or perhaps Traci or Nancy, will show you how to operate the computer and other equipment, how to locate and view the exhibits on the computer, and how to print the exhibits -- well, they won't be printable, so disregard that part.

THE COURTROOM DEPUTY: They'll have hard copies of the exhibits as well.

THE COURT: You'll also have hard copies of the exhibits.

You will also be provided with a paper list of all exhibits received in evidence. You may request a paper copy of exhibits received in evidence. You're going to get that already, so disregard that.

If you need additional equipment or supplies or if you have questions about how to operate the computer or other equipment, you may send a note to the bailiff -- and I'll be swearing Traci and Nancy in as bailiffs before you retire to deliberate.

The note should be signed by your presiding juror or by one or more members of the jury. Again, using your number rather than your name. Do not refer to or discuss any exhibit you are attempting to view in any note that you send out.

If a technical problem or question requires hands-on maintenance or instruction, a court technician or one of the bailiffs may enter the jury room for the sole purpose of assuring that the only matter that is discussed is the technical problem.

When the court technician or any nonjuror is in the jury room, you should not deliberate. No juror may say anything to the court technician or any nonjuror other than to describe the technical problem or to seek information about the operation of the equipment. Do not discuss any exhibit or any aspect of the case.

The sole purpose of providing the computer in the jury room is to enable you to view the exhibits received in evidence in this case. You may not use the computer for any other purpose. At my direction, technicians have taken steps to ensure that the computer does not permit access to the internet

or to any outside website, database, directory, game, or other material.

Do not attempt to alter the computer or obtain access to such materials. If you discover that the computer provides or allows access to such materials, you must inform me immediately and refrain from viewing such materials. Do not remove the computer or any electronic data from the jury room, and do not copy any such data.

We're almost done.

If it becomes necessary during your deliberations to communicate with me, you may send a note through the bailiff, signed by any one or more of you. Again, using your numbers. No member of the jury should ever attempt to communicate with me except in a signed writing. I will not communicate with any member of the jury on anything except -- on anything concerning the case except in writing or here in open court with the parties present.

If you send out a question, I will consult with the lawyers before answering it, which may take some time. You may continue your deliberations while waiting for the answer to any question. Please remember that you are not to tell anyone, including me, how the jury stands, whether in terms of vote count or otherwise, until you have reached a unanimous verdict or have been discharged. Do not disclose any vote count in any note you may send out to me.

A verdict form has been prepared for you. It's a pretty simple two-page form. It simply says: We, the jury, duly impaneled and sworn in the above-entitled action, upon our oaths, find as follows.

And then for each claim, there's a question of whether or not you find for the plaintiff on that claim, and there's a place to check yes or no on each of Mrs. Hyde's two claims and then on the loss of consortium claim.

If you find liability on the claims, there's a place for you to indicate the amount of damages that you award, and then, finally, a place whether -- where you indicate whether or not you decide that punitive damages should be awarded. And if you say yes to that, then we'll bring you in for some brief additional argument and evidence before you actually set the amount.

And the verdict form is then to be signed by the foreperson using his or her number.

Counsel, are there any corrections or additions to the instructions?

MR. LOPEZ: No, Your Honor.

MS. HELM: None for the defendant, Your Honor.

THE COURT: Okay. All right. We are going to then proceed with Mr. Lopez's closing argument.

The plaintiffs are allowed to make a closing argument, then defendants make a closing argument, and then plaintiff

gets a brief rebuttal argument since they have the burden of proof.

Mr. Lopez, since -- before you start, let's let everybody stand up for a minute so --

MR. LOPEZ: I'm going to test this, Your Honor, while --

THE COURT: You can test that. That's fine.

All right. Mr. Lopez, you may proceed.

MR. LOPEZ: Thank you, Your Honor.

Good afternoon, ladies and gentlemen. Your Honor.

First, on behalf of our entire very dedicated and committed legal team that represented Mr. and Mrs. Hyde, we want to thank you for your service as jurors.

You know, this isn't the first case that many of us have tried. We've tried cases, you know, in different parts, we've seen -- of the country. We've seen jurors. I can tell you this, I've never seen a jury pay as close attention to some very complex things and take as much notes as you have.

So one thing you have is your notes. You have the evidence. And my job right now is to, in a very short period of time, try to help maybe refocus you on what we believe are the real facts in this case and now apply to the law.

So a lot of this stuff you were hearing was just in a vacuum. I mean, what -- did it have any relevance? What did it really mean?

Now, the judge has given you the elements of the cause of action in this case for a design defect, and we, as the plaintiffs, have the burden to prove either -- not both -- that there's strict liability for design defect or negligence for design defect.

I want to thank my team. They worked hard.

Your Honor, you and your staff, appreciate all the accommodations. And we know that you and your staff work hard as well.

Now, there are two places we are all equal in this country: the ballot box and the courtroom. Two places where status, power, and wealth do not influence the outcome. It's a safe and guarded place where strangers come together and effectuate change for the good of society.

Your decision in this case may very well be the most important vote you cast in any election. You have an incredible power that you yield to make decisions that not only affect this case but could affect the type of standards of testing and design and conduct that we expect of not just medical device companies but, you know, companies that make products that are dangerous. What do we expect them to do?

I mean, what do we expect of automakers? Do we walk in and we see a pretty brochure that says it's taken strength and stability to a whole new level, and no one told us that they never tested it in the real world? They really don't know

how it's going to operate. They don't know whether -- they don't know whether or not this vehicle that they just produced has taken away, through new design, a horrible history that the vehicle before it had. They have no idea.

And you walk into a dealership and you don't know that you're going to be an experiment with this vehicle when you start driving it. You're not going to know whether or not this vehicle has the same tendency for its suspension to break or for it to roll over or for it to skid out of control because of design defects that a prior device -- or a prior product had or a prior automobile had, or whether or not the redesign actually put in new risks that the other automobile didn't have.

So, you know, this is not just about medical devices. This is about the standard that we all expect as a community. And God bless the law. The law guides you through what those standards should be.

Your verdict will affect the paths that corporations like Bard should choose when faced with choices between patient safety, people's rights, and their commercial interests. You have the power to choose the paths that you, in your collective wisdom, believe best protect people from getting hurt by dangerous products, that products are not properly tested, that products where a company doesn't know, because they didn't do a clinical trial, how that product is going to perform once unwitting consumers start to have them implanted in their

bodies.

And they don't even have the decency to say, you know, we don't know, so they could break. They could migrate. They could have a lot of problems. You need to come back to your doctor and have him look specifically for that. Not just come for a follow-up visit to see how you're doing after the surgery, but tell the doctor, by the way, we don't know what's going to happen with this device. We don't know whether it's going to break, whether it's going to migrate, tilt, perforate or put your patient at risk, but we know that our prior device did that.

So maybe do what Dr. Asch did when he had his patients and he didn't know, and that is to have them come back and look and see what happened. Why do you think that migration was found in Dr. Asch's study? It's because they were being controlled -- they were in a controlled clinical trial.

And that lucky man, that Patient No. 9, the only patient in that study that got hit with a clot, where the clot started to move the device 4 centimeters towards the heart, what would have happened to him had he been a patient in the open marketplace where he wasn't in that kind of controlled environment?

Well, we know what happened. The same thing happened with the Recovery filter once it was on the market. And that device was not taken off the market until Bard had their next

one ready to launch.

Just remember that every time you hear about statistics, those are human beings. This case is not about whether or not the statistic is .6 percent times a hundred -- which they don't do. They're going to stand up and tell you our rate is, you know, from the MAUDE database over our sales, something they say they can't do -- or we can't do, but they do it and tell you this is our rate, .16.

And their own medical director, Dr. Ciavarella, where was he? He was on videotape. He didn't come here to address you on this. He said 1 to 5 percent, they have to assume this is happening. And they don't do that. They're going to tell you that that's the actual rate.

Now, the paths that you will be able to choose as jurors is, number one, is you can say it's fine with us if companies knowingly sell potentially dangerous products before knowing how dangerous they will be once used in real live human beings.

Or once they find out, when they put it on the market and they find out that all that bench testing we did, all that wonderful bench testing that was done, didn't reveal itself the same way in human beings, and they ignore it. Then they do testing and find out, well, we better test this thing the way it would really be in a human being.

Remember Mr. Tessmer was here? And he said, well,

maybe we should test this thing not at 104 degrees, because not everyone's going to have a fever that gets these things. Most people are going to have normal body temperature. Let's test it at normal body temperature.

Well, it failed on the bench three times. And what did Bard do? They kept it on the market and allowed catastrophic injuries with the Recovery filter to continue. And you'll see some of that evidence.

This is the one that should concern us all. Do we condone experimenting and testing of potentially dangerous products in human beings without their consent, and the protection each would get if in a monitored and controlled clinical trial?

They didn't tell Mrs. Hyde that, we're still trying to figure out what's wrong with this device. They didn't tell Mrs. Hyde that, by the way, we've been trying to figure it out.

Remember the root cause analysis? You're supposed to figure out what's wrong with this thing. We still don't know. But we think we might have another product coming on the market that might be better, might keep you safer. And they don't tell her that.

They want to talk about the IFU. This case is not about an IFU. This is -- if it is about an IFU, it's about the fact there should have never been one for this device, meaning it should have never been on the market, and they know it.

Dr. Tillman said it. Dr. Ciavarella said it. Their own doctor, their own medical director, said, when this device was on the market for three months, why are we selling the G2 with all of these problems when we have the SNF?

And I asked him at his deposition, I said: What you're saying is, let's stop selling the G2 and figure out what's wrong with it. In the meantime, let's sell the SNF. And he said yes. The medical director.

Why would you not follow the device -- I mean, the advice of the only medical person on your staff who really knows about patients? The only person who took the oath, "First do no harm."

I'll tell you why, because they only had a permanent indication. And you heard it, aggressive marketing, and I'm going to show you some of that evidence in a little bit.

They knew in order to expand the marketplace, they had to make it retrievable. And so what did they do? Instead of stop -- stopping the sale and marketing of the G2 filter that they represented to the world in their brochure -- you've seen it. They never changed that brochure. We've taken strength and stability to a new level.

I mean, my goodness, I mean, if there is anything in this case that's been proven, not just by the weight of the evidence but beyond any doubt, is that if it took strength and stability to a new level, they should have said to a lower

level, not to a higher level. They knew they had two or three fractures in the Simon Nitinol filter in 20 years. And in six months, they had already well surpassed that.

But here was something that happened with the G2 filter, the G2X, and the Eclipse, and all these retrievable filters that was not in the medical literature. And remember Dr. Grassi testified. You know, they want to say these are the guidelines.

He did a search of the world literature. Right? And in 2001, 2003, when he reported this, he found four fractures in the entire world literature, and none of those fractures did what this device does. There was nothing written in the literature about fractures migrating to people's hearts and lungs.

And you've seen this -- the statistics. Mr. O'Connor showed you some of those this afternoon. That's what this company knew.

There was no such thing as a Type A or Type B fracture, and still they started making the G2, G2X, and Eclipse filters, that whole family of filters, including the Recovery. And they want to say, well, doctors knew about this. It's -- a fracture is a known complication. No. I'm sorry.

Vehicles can roll over, but if your vehicle rolls over in a simple maneuver because you haven't tested it and you know it's defective, and you know maybe even in some of your

simulated testing it rolls over at low speeds, or the suspension breaks in a normal operation that puts you at greater risk than other automobiles you can buy, including one that they sell, you need to know that.

But the problem is, that vehicle would never be on the showroom floor. They couldn't sell a vehicle like that. Say, by the way, you know, we've got this new one. It's prettier. We've put a lot of time and effort into it. It's got a couple other nice features to it. But, let me tell you, we've been testing it and it's a lot more dangerous than the device -- than other devices we have. No one -- I mean, that vehicle -- that product should not be on the market, and they know it.

Here's the other thing that's important to remember in this case. These internal documents that Dr. -- Mr. Ganser, I think Mr. Carr, said all this important safety stuff about their internal statistical analysis about risk compared to their Simon Nitinol filter and other filters on the market, their bench testing that shows that the thing's failing, their own -- not just in human beings, but it's not even performing safely in a PVC pipe and a sausage casing. That kind of stuff, they don't share. It's proprietary.

Well, guess what else is proprietary? All those documents you saw in this case. Those are all confidential documents. Let me tell you how confidential they are. They don't show their own experts these documents. I mean, their

own key opinion leaders. Dr. Trerotola, who's been their consultant for I don't know how long -- he said he went way back to the Recovery filter -- he's not seeing the internal documents. Well, guess what, ladies and gentlemen? You have. And you know what the truth is.

And, you know, if you want to not listen to any of the experts in this case, you want to tell both sides they wasted their time and money putting on experts, look at the evidence. Look at the facts in the case. Look at what Bard knew and the evidence out of the mouths of their own witnesses and their own documents.

The conclusions will be clearly that this company knew what they were doing. They violated Mrs. Hyde's rights and interest. They knew that they were putting her at risk. You know why? Because they needed to get that retrievability. I'll come back to where I was a few minutes ago.

They focused on retrievability, not on fixing their permanent device that they knew was -- where Natalie Wong said there was a statistically significant increased risk of a serious injury from caudal migration that included death and serious injury.

They didn't focus on that permanent device, the device that got cleared in fixing it, which they should have done. Because you know what, if they had to do that, no retrievability for them. No EVEREST study for them.

So what do they do? They do the EVEREST study. Remember, Dr. Kandarpa testified. You saw some of the documents. The EVEREST study was for retrievability only. They didn't even have the decency to say, well, you know, we've seen a lot of serious problems with this device, with doctors reporting it to us, fractures, perforations, you name it. More than our Simon Nitinol filter, other devices on the market.

And instead of telling Dr. Kandarpa and the clinical subjects in the EVEREST trial, they continued the EVEREST trial. Because they wanted to get retrievability. And they got it, because they were able to prove that 58 out of 61, they were able to remove it successfully.

And FDA, they put -- 1,500-page document they sent to the FDA and they said at the end, this thing's safe and could be removed. That was the only issue in front of FDA at that time, was whether or not this could be retrieved. It was not a long-term study.

I mean, I was shocked the other day. I heard Mr. Carr say that the Asch study was a long-term study for safety. I mean, Dr. Tillman said it wasn't. Their own expert. More importantly, Dr. Asch said no, no, no. This thing was to see if I could take this thing out within 12 weeks.

And he wants you to believe that was a long-term study. I'll tell you why he wants you to believe that. Because in one of the exhibits that you have -- I'm sorry, I

don't have the number, but I'll tell you what it is. It's your first submission to FDA for a retrievable device.

And you know what they say in that submission, in the very last part of it, that they know the FDA is going to focus on, because the issue is substantial equivalence? They say Dr. Asch's study established safety and effectiveness as a permanent device.

I mean, that is as big a whopper as you can possibly have when their own expert, their own people before them, have all admitted -- there are other people that have admitted, you've heard the testimony, there's no way that was a long-term clinical trial. In fact, they told Dr. Asch they were going to do one before they tried to market it.

Their long-term clinical trial for the Recovery filter was just putting it out in the open marketplace and having catastrophic injury after catastrophic injury occur. Then they test it, find out it's not even performing to their performance specifications for foreseeable uses. They leave it on the market.

Now, I know this case gets a little complicated because we start talking about the FDA, you know, substantial equivalence, and that's why you're on the market. Well, every important witness in this case, both experts, Dr. Parisian and Dr. Tillman; Mr. Ganser, the vice president of regulatory science -- I mean, probably the highest level person who

testified in this case, said that once you're on the market and you clinically are not performing substantially equivalent to the Simon Nitinol filter, you got to stop selling it. You're adulterated.

Well, they couldn't take the Recovery off the market because they couldn't use an adulterated product as their predicate device.

And, by the way, it doesn't matter. Everyone agrees that all of these have to be at least as safe and effective as the Simon Nitinol filter. It would make no sense if you could have the original standard of safety and effectiveness be a product that's been proven safe for 15 years and then lower the standard as the devices get worse as you go.

Okay. Mr. Ganser said it, Dr. Tillman said it, Dr. Parisian said it, and others have said it, that your job starts after you get clearance. Okay. Whatever the minimum requirements are for you to be able to put it on the market, your job starts when you start selling that product.

And as soon as you have evidence that that product is not as safe and effective as the product that allowed you to get on the market, which they all go back to the Simon Nitinol filter, you need to stop selling it. And you need to go to FDA and tell them that, okay, so FDA knows.

They kept Dr. Kandarpa far away from FDA on the EVEREST study. Because, remember, he wanted -- he wished he

had the power to stop the study. He told them they ought to reconsider and reevaluate this. He didn't even know it was on the market at the time.

So let me take you through some of the evidence in the amount of time that I have. And I'll tell you that, you know, one of the things I really enjoy about doing this, and it's been almost 40 years, is I get to meet, you know, really, really great people.

And I just -- I love being able to give people like the Hydes an opportunity to take on the likes of a C.R. Bard, an international company. I do. I mean, that's -- I've been doing it for that long.

This is not about Mrs. Hyde's encounters with the FDA, with the Society of Interventional Radiologists, with other IVC filter manufacturers, or even Dr. Henry. This case is about her relationship and the trust and faith that she put in C.R. Bard and Bard Peripheral Vascular, the defendants in this case.

And it's not about whether the FDA did something or didn't do something. You heard the experts. The FDA doesn't design these things. I mean, most of the time they were talking to a chemist or a nurse or someone who's not -- I'm not putting those --

Lookit, the FDA's a wonderful organization, but they're only as good as the honesty and the integrity and the

information that they get from companies, especially in a 510(k) process. I don't fault them for anything in this case, and they're not a party to the case. This is -- you have to look at the conduct of C.R. Bard, of Bard, and her duties to Mrs. Hyde; and more importantly, their duties under the law that the judge read to you.

I know, lookit, as you go through this trial, you get -- I mean, I was having -- it was like -- it's an emotional roller coaster, believe me, even for the lawyers, and I'm sure for you. You hear -- you know, we get up and say something and they make a different point, and you're wondering, you know, who's making the good point.

Well, I can tell you this. This case is not about an IFU. This case is not about FDA. This case is not about SIR guidelines, or anything else. Not about statistics. It's only about statistics because they created statistics that should have never been created. That's the only relevance statistics have in this case.

This is their -- Bard's duty to Mrs. Hyde as an ordinary consumer. A consumer who trusted that she was getting a well-studied, thoroughly tested, clinically proven device that she believed was actually going to protect her. Give her an extra barrier, an extra -- you know, she was on anti -- she had a protein factor that caused her to be -- have -- not form clots. She was prone to clots.

She was on anticoagulants, and the doctor who put it in said, well, I want a temporary filter just in case, or a retrievable filter. But guess what? He did what Bard was marketing them to do. You can keep this in for your life. It's an added protection. It's a permanent device.

It's just not as safe and effective as the -- nowhere near as safe and effective as the device that allowed them to get marketed.

Now, no one -- before I leave that and get into more of the evidence, remember this: Natalie Wong, again, someone who didn't testify in the case -- they brought Mr. Modra, who wasn't even there at the time. He got there -- how dare he come in and criticize the work one of his own employees did, or try to explain it away. Let Natalie come in and do that.

You know, but they didn't -- that didn't happen. So Natalie Wong, who was a lead engineer on some of these things, not Mr. Modra, in -- I think it was March, April, May of 2004, the Recovery filter was behaving exactly the way Dr. Asch's study was expecting it to behave but worse, because people weren't being monitored, and the device was wreaking havoc out in the clinical world without people realizing it was going to.

She did an analysis of the competitors of Bard. She did an analysis of the Simon Nitinol filter and found a statistically significant increase in fatalities of the Recovery filter compared to the Simon Nitinol filter and

every -- and five other competitors. What did they do? They left it on the market.

You know, they're going to get up and say this case isn't about the SNF and the Recovery filter. You're right, it isn't. But it is. Because these are the two devices that allowed the G2, the G2X, and the Eclipse to come into Mrs. Hyde's life, and those device -- that Recovery device should have never been on the market, and they know it.

Here's what -- if you don't -- I think I'm going to capsulize the two years this -- the Recovery device was on the market.

Remember this testimony by Jason Greer, who was talking to the architect of the Recovery filter.

Did I do it right? He said -- not playing.

Let me read it. You weather the storm as well as anyone, he's saying to Janet Hudnall --

(Video played.)

MR. LOPEZ: That's how they described the two years with the Recovery filter.

Okay. Let's -- let's fast-forward, 2008. Because this kind of grabs the Recovery era and the G2 and the G2X era. And here's how -- this is a self-assessment of Bard, probably their engineers. I can't remember who did this. But this was their weaknesses.

Lack of thorough understanding, dynamics of caval

anatomy. In other words, they knew they didn't even understand where this device was being put in.

We have historical reactive/evolution design mindset, meaning they wait and see what happens in the open marketplace. Then they'll look at the design and see whether or not it's time to maybe do something about it.

Product complications, forcing focus on reactive designing. There it is again.

Limited understanding of user needs.

Now, I didn't read the strengths part of it, but they did not include in there marketing safe and effective products.

And then G2 -- so here's what -- got it.

Due to catastrophic injuries reported immediately with the Recovery filter, they started to redesign it to create the G2. And, again, this is the Recovery. Catastrophic. From January 2002 to June 2004, 17 reports of limb fracture.

That's a little misleading, because if you remember the testimony, they didn't really do their full market launch until January of 2004 because they wanted to wait for retrievability.

But here's what was different about the Recovery filter. And by the way, everything I'm saying about the Recovery was true about the G2.

A total of 20 arm fragments were reported in 14 cases. Three patients had detached hooks and arms (11 of 20 arms

remained in the patient), and in six patients, 30 percent, the detached arms migrated to the heart or lungs.

Nothing in the medical literature about this. Or you would have seen it in 2004.

They refer to the SIR guidelines. Well, everyone knew about fractures. No. Not everybody knew about Bard product fractures and what happens when a fracture of their device in this direct highway to the heart.

The root cause of the fractures has not been determined. You know what that means? That means they have no idea why. And they think if they have no idea why, they can just keep it on the market and still try to figure out. But you're going to see some testimony, if I have the time to do it, Natalie Wong, it was 2012, they still don't know why their devices fracture more than others fracture on the market.

And then Dr. Ciavarella: There's no way to predict which patients will develop this complication. More frequent monitoring of the filter, once placed, may facilitate discovery of abnormal placement or indeed of a fractured filter.

Why did they not listen to the only medical doctor on their staff? And they still haven't. Why didn't they do that with the Recovery or the G2, the G2X? After the experience in the EVEREST trial, where they knew that these things were moving all over the place.

You know, they talk about the guidance document as

well as the guide. Well, the guidance document tells them they're supposed to count 5-millimeter migrations. They only counted the 2-centimeter ones.

And you know what Dr. Kandarpa said? There's 51 percent of the time these things were moving. He was concerned about stability. It didn't matter whether it was 5 millimeters or 2 centimeters or 5 centimeters, because he knew that the 5-centimeter ones, if not in a controlled trial, were heading to 2 centimeters. And he told them he was concerned about the design of that device, and they ignored him.

And Dr. Ciavarella wrote: One could consider providing summary information concerning the analysis of reporting rates to physicians in the context of the limitations of the data. Further work into the collection of survey data from surgeons or payors might be explored.

The medical doctor was recommending that in 2004. And in 2011, they still hadn't done that.

Dr. Ciavarella was saying, let's give these people a chance for their doctors to find out whether or not they have a fracture or a device that's moved that's putting them at an increased risk.

Don't you wish -- doesn't Mrs. Hyde wish that Bard would have told her doctor, told her, in the patient brochure for the G2X, where it says "This is the only device you'll ever

need," by the way, these things can move. If they move, they could really cause some additional problems. You need to come back and have your doctor figure out whether or not this thing's moving, perforating, and/or puts you at risk of fracture.

Because Dr. Ciavarella told the rest -- everyone else at Bard that maybe we ought to do that, to help maybe save people from what she went through, which they minimize, you know. You're okay now. You're asymptomatic.

So here's -- again, this is Dr. Ciavarella. You know, they actually did an analysis. They hired Dr. Lehmann, who they later fired from the EVEREST study --

We got to take that down.

So they like to say, well, the SIR guidelines are the measure of what doctors accept and what's acceptable. They know that's not true. They gave it to FDA and told them, don't worry about that. These are all within the acceptable rates of complications by the Society of Interventional Radiologists.

Well, Dr. Grassi came here and said, no, they're not. They don't even deal with these devices. These deal with devices that are 10, 20 years old. These are not acceptable.

Here's what Bard knew what was acceptable to doctors; this priority accounts. They knew that doctors were stopping -- they just heard of a migration and they stopped using the device. Not, oh, well, wait a minute. Let me look

at the SIR guidelines that are -- deal with the devices that are not on the market.

Okay. So I forget what Mr. Carr told them, product life -- no. You know what this is? Safety problem after safety problem after safety problem, design problem after design problem after design problem. And they still don't know if the Meridian has solved the problem.

And the one device they don't talk about is the Denali. And that -- and the Denali is finally in a clinical trial. We still don't know.

And here's the evolution again. These all -- every one of these is not a company saying, well, let's make our really great product better. No. Let's make our unsafe, our adulterated, our misbranded product that we're telling the world has taken strength and stability to a new level, we need to make it safer.

Okay. Let me walk you through the law. And you got these instructions. And the first instruction that -- the first cause of action we have is strict liability, a design defect.

So here's that law. A foreseeable risk of harm posed by the filter's design. We know those are foreseeable risks. They even admit. I mean, they have a laundry list of these risks. But they think if you put a laundry list of these risks in this fine-print IFU like auto manufacturers probably put in

their manuals that vehicles can roll over, that if theirs does it worse, no harm, no foul.

Could have been reduced or avoided by the adoption of a safer alternative design, and the omission of the alternative design renders the product not reasonably safe.

Well, you saw the numbers. You saw the statistics. There's no other product on the market as of 2010 that had more -- I mean, by a huge number. I mean, some of their competitors had zero Type A fractures. That's what I want to know about. That's what patients want to know. They don't want to know does this thing fracture and stay where the device is. They want to know, does this device fracture whatever hundred times where it actually migrates to the heart or lung?

And by the way, tip of the iceberg. Dr. Feigal agreed and Dr. Ciavarella agreed, if they're seeing a hundred-plus Type A fractures and a hundred-plus Type B fractures, this company can't come in here and say, well, that's unreliable.

Yeah, it is unreliable. They should be assuming there's a thousand of those. Maybe 10,000 of those, because, I mean, they brought it out with their own witnesses. They're asymptomatic. They wear that like a badge. Well, no. That's terrifying, that these devices could be behaving the way that they behave and you don't even know it.

THE COURT: Mr. Lopez, you asked me to prompt you at 35 minutes and 45 minutes. And it's now 35.

MR. LOPEZ: Thank you.

There's a reasonable alternative design that could have reduced or avoided the risk of harm associated with the device, and the device is not reasonably safe. You saw -- I mean, they were -- Meridian, Simon Nitinol filter. Don't forget the testimony, after six months, this thing converts to a permanent device. Plus, no one gave them a pass on it not being safer than the Simon Nitinol filter after they got the retrievability.

You saw the evidence on OptEase. Just look at the data on the OptEase in that 2010.

Okay. Here's the Meridian. Boy, didn't Mrs. Hyde wish she could have seen this? That the Meridian was predicting that caudal migration would have that much of a difference between the device that she got and other -- and the device that Bard already had designed.

The OptEase, they compared themselves to the OptEase, and they come in here this morning and bash the OptEase, yet they're using it as a measure of safety when they're designing the product.

They had a lower complaint rate for caudal migration than the G2, G2X, in the MAUDE database.

And here's Dr. Ciavarella again, someone they just didn't listen to: The G2 filter is a permanent filter. We also have one, the SNF, that has virtually no complaints

associated with it. Why shouldn't doctors be using that one rather than G2?

And here's that chart. These are their numbers. We didn't create this. We didn't go into their files and put these numbers together. This was in their files.

And here's Type A fractures, something that didn't exist in reality at Bard or anywhere else until they started selling their Recovery, G2, G2X device.

Embolization of the fragment to heart or lung. Migration of the fragment anywhere outside the vasculature. Any additional surgery except filter removal or medical treatment. And then the other one is still fragments that are broken off.

And just look at the numbers. 195 Bard fracture A, and this is for a time period -- I think it's 2005 to 2010. 195 to 13. And look at ALN, another one of their competitors. Zero. Cook, Cordis, zero.

And then I heard Ms. Helm get up and say, well, they didn't show you the percentages. Well, look at the percentages. Compare the increase, the .5 versus the .001. And figure it out for yourself whether or not what was being reported to them was 50, a hundred times greater risk.

So what we did is we brought in Dr. Betensky. I mean, if I ever felt like a mule at the Kentucky Derby, it's when she read her credentials. I mean, what an incredibly credentialed

scientist she is, and they didn't bring anyone here to combat her and to say that what she presented was wrong.

G2, G2X penetrate 10 times more than SNF. The G2X and the Eclipse migrate 18 to 20 times more than SNF.

And by the way, the first part is they were predicting it, and in reality it was worse than what they had predicted. And she made that statement about, you know, for her, someone who works with companies like this, who does these analysis, that she was -- the magnitude of these risks were concerning to her about patient safety.

And then the intended implant duration is for the life of the patient. At what point must the filter be considered permanent? Six months.

Well, they knew that from the EVEREST study. And how did they market it? They marketed it as safe -- can be safely removed at any time. They had no science to back that up. It didn't say that in the clearance letter that they could say that. They just said it, because 510(k) products can do that.

Dr. Henry: Safe to use as long-term and permanent filter. Yes. It was temporary, but he said they were just leaving them in so -- but he said they were just leaving them in, so it would be a permanent filter for me.

Negligent design and testing. Here are the elements. A person is negligent when he or she fails to exercise ordinary care. Ordinary care is the care a reasonable person would use

in similar circumstances.

Ordinary care would be just, you know, test the thing. Figure out what's wrong with it, and stop selling it until you figure it out. Because they knew it was causing -- I mean, I don't know how clear -- how much clearer it could be. Unacceptable risk of serious injury, their own internal analysis.

It's the manufacturer's duty to exercise ordinary care in the design of its product so as to render the product safe for its intended use. Not FDA's, not the SIR, not anybody else.

Dr. Tillman, Dr. Parisian said no, no, no. FDA doesn't test these. They don't design them. The company is a hundred percent responsible. I mean, they could go to FDA every day. If they're selling a dangerous product, they're responsible.

If they want help from FDA, they want guidance from FDA, then show them what you got. You know? People that have nothing to hide, hide nothing. And why are they not sharing with them their internal risk analysis? Why are they not sharing with them the Type A and Type B fractures that are unique to their product?

And then when they go to get the device on the market, they -- let's see. Did I go too far?

Oh, here we go.

So they knew that they really needed to be as safe as the Simon Nitinol filter, so they tested it. Well, guess what happened? It failed.

So they said, well, we're not going to get substantial equivalence from the FDA with a failed test on migration. So what do they do? They changed it to substantially equivalent to the most dangerous IVC filter on the market at the time, the Recovery filter.

Let's hear from Mr. Ganser.

(Video played.)

MR. LOPEZ: And here's what they did. Changed from Simon Nitinol filter to the Recovery filter. Now they passed. Now they can go to FDA and say, look what we got. We're just as good as the Recovery filter.

And then, of course, as -- again, these are internal documents that nobody got to see, FDA or anyone, until now. Just because we didn't think the answer would support our design change as a viable option, we chose to run the test -- we chose not to run the test. That's a pretty important word.

Anyway, the document says we chose not to run the test, because they knew it was going to come out bad for them.

Now, you know, Dr. McMeeking. You know, I -- Dr. Briant comes in here, very charming guy. Stanford, you know, I like Stanford. But here's the bottom line. Those things that Dr. McMeeking was saying were predictable from the

way he thought they should be tested, happened.

I mean, Dr. Briant didn't come in here and -- they didn't hire him to run different tests. You know, Dr. Briant didn't say those things that Dr. McMeeking was saying was wrong with the design of the device didn't actually happen. They actually happened.

This is Natalie Wong.

(Video played.)

MR. LOPEZ: And here's what happens when you don't know what the root cause analysis is.

(Video played.)

MR. LOPEZ: Dr. McMeeking used Bard's own data and worst case scenarios. And Dr. Tessmer did that, too, and he saw that they all failed.

Asch Recovery study. Retrievable study only. Not designed -- we already talked about that.

Okay.

(Video played.)

MR. LOPEZ: I mean, there are so many district managers that sell these devices that Mr. Randall this morning didn't know how many and didn't know most of their names. I mean, they had their people out there in force selling this product.

THE COURT: Mr. Lopez, 45 minutes.

MR. LOPEZ: Thank you, Your Honor.

And then we've talked about this, the EVEREST study, what was revealed in the EVEREST study. But please pay attention to this. This is all in trial Exhibit 1222. They knew that if they put in the design changes that needed to be designed, they were predicting that they could reduce these complaints, these problems by 78 percent.

And they didn't do it. They didn't tell Mrs. Hyde that she was at an increased risk because they didn't -- hadn't done this or that the Meridian or some other devices out there were coming on to the scene.

Dr. Kandarpa. Already talked about Dr. Kandarpa.

Lack of adequate testing. Dr. Briant, again, criticized Dr. McMeeking that there was a relationship between tilt, perforations, and fractures. Yet Bard's internal documents all say that. I mean, I heard Mr. Randall this morning say it.

Let's hear from Mr. Ganser.

(Video played.)

MR. LOPEZ: There were defects in the design of the G2 that led to Dr. Ciavarella's 2006 HHE where he said that the problem was critical.

So let's talk about punitive damages. I think -- I think that's -- the evidence in this case clearly shows that this company needs to be deterred from that kind of conduct in the future, from using people like Mrs. Hyde and others for all

these years in an experiment that they don't even know they're in.

Punitive damages may be awarded if you find that the defendant, in an intentional disregard of the rights of the plaintiff.

I mean, what more rights does a human being have than to know that you're selling a product that's defective, you've acknowledged it's defective, you've acknowledged it has to be fixed, you acknowledge that it's creating serious injury and harm and breaking more than any other device on the market? What other right -- what more rights do people have than to either know that or to not expose you to a device like that?

No one would have assumed that. Everyone would have assumed that they were getting the safest device possible. They would have assumed that what Bard was saying to people, that they took the G2, G2X, and Eclipse from a safety -- I mean, from a strength and stability standpoint to a whole new level, meaning it was better than any other device on the market.

There's no requirement that the defendant intended to cause harm to Mrs. Hyde. Of course -- I mean, of course they didn't. I mean, they didn't even meet each other until this case.

But the purpose is to punish a wrongdoer or deter the wrongdoer and others who are engaging in similar conduct in the

future. Actual -- evidence of actual harm to nonparties may help to show the defendant's conduct that harmed the plaintiff also posed a substantial risk. But we know about all the other folks that are out there. I mean, how many are out there that are asymptomatic who don't know this could be happening to them?

We knew -- I mean, it doesn't get any clearer than this. This is not, you know, an expert. This is not one of our witnesses that we brought in. This is Bard saying, we knew very little about the long-term clinical performance of this device when we launched it. After a year of commercialization, there are still many questions that need to be answered. And the response to that was to ramp up their sales.

The G2 is a permanent device, and we already talked about this. This is Dr. Ciavarella. He said in his testimony, when I presented this to him, what he meant by that is why don't we stop selling the G2 until we figure out what's wrong with it.

Well, I don't know where that went other than the fact that they -- their step was to expand the marketplace. And here's what's incredible, is they knew how to fix it. This is in April of 2006. They knew that the Greenfield filter had experienced the same thing, and you know what the Greenfield did? They flipped two hooks to prevent caudal migration.

And then as they continued to evaluate the G2 against

the Recovery, which they should have been doing against the Simon Nitinol filter. One of the things you're going to see, that spreadsheet we showed you with all those Type As and Type Bs, they don't put the Simon Nitinol filter on there to compare it. I don't know why. Other permanent filters are on there, but they don't put the Simon Nitinol filter.

Because you know why? The Simon Nitinol filter had three fractures in 20 years, none of which went to the heart or lung.

(Video played.)

MR. LOPEZ: Dr. --

(Video played.)

MR. LOPEZ: Don't we wish they would have listened to the only medical doctor on the team.

Oh, I went the wrong way. Sorry.

Dr. Kandarpa. Do I press it again to play it?

(Video played.)

MR. LOPEZ: They kept it -- they didn't tell anybody that. Nobody.

Maybe the most important document on punitive damages in this case is they defiantly, after all that data they had from EVEREST, from their own internal analysis, they continued to market this device and all of the devices after it that were based on the G2 as taking strength and stability to a new level, as increasing migration resistance, improving centering,

and enhanced fracture resistance, while internally they were creating PowerPoints and having discussions about how they needed to fix their design to deal with those problems.

SIR guidelines, I've already talked about that. I don't know why we even talk about them in this case. This is a design defect case. SIR guidelines don't have anything to do with that.

FDA, they don't design these things. They're not responsible for the design. They're not responsible -- they're not the ones responsible for preventing people from being exposed to a dangerous product or from -- they're not the ones responsible when they expose people to a product where, you know, the people are part of, you know, their experiment, part of figuring out whether or not these things work.

(Videos played.)

MR. LOPEZ: I mean, they don't get any higher in the food chain, of all the people you've heard from, than Mr. Ganser.

Okay. I'm going to skip to the -- Mrs. Hyde's filter. This still baffles me as to why they just don't admit it was a G2X. I think it's because they knew the Eclipse was on the market and they didn't take the G2 or the G2X down. And they knew -- they at least thought that the Eclipse might have given Mrs. Hyde a better opportunity of it not fracturing, but look at the evidence.

I mean, they brought in some invoices that are like, so what? I mean, we know that the G2 was still in the market and G2X.

So the implanting doctor, Dr. Henry, calls it a G2X. Dr. Morris, their expert, didn't call it an Eclipse or -- he called it a G2X. The sales force, Tim Hug, G2X.

And remember when Dr. Henry was being cross-examined by the defense attorney, Bard's attorney? She wasn't asking about the Eclipse. She was asking about the G2X.

And what did Dr. Kuo call it? One of the foremost experts in the world in looking at these things and taking them out. He thought on the x-ray it was an Eclipse, because they look the same on an x-ray. But what did he call it in his op report when he took it out? A G2X.

That's Dr. Henry's testimony about that.

Okay. Now, let me talk about Lisa Hyde and her injuries. She -- I mean, this is where it gets difficult for me because I have to somehow or other make you understand, you know, four years later, what she went through. And for you to figure out, you know, she's sitting there. She's with her husband. I mean, she's retired. She works for this wonderful charity. They got three lovely children, two adopted, one of their own. Seems like life is great for the Hydes.

But we have to talk about the three months of terror and horror that she went through and to take you back to that

time so that you can feel what she went through and figure out, what should Bard pay for having done that to her. For giving --

I mean, think about this. You're in the -- you're looking -- going through the newspaper, and you see the want ads. And it says there's a -- I want you to give up your entire summer because I want to see -- and we're going to put a metal piece of wire in you about an inch long, and we're going to put it through your -- we're going to put two of them through.

We've got one touching your spine and one touching your aorta where, you know, people -- and we don't know whether or not it's going to perforate the aorta, the largest artery in the body. We're going to put another one in the right ventricle of your heart, and we're going to see what happens over the next three months. We don't know. We've never studied that.

And we're going to pay you $5 million. Give up your summer.

And you, you know, wait a minute. Wait a minute. You're telling me that you're going to -- you don't know what's going to happen? You don't know whether or not I'm one heartbeat away from that little piece of metal perforating my heart?

And Dr. Ciavarella -- that's why I played

Dr. Ciavarella's deposition, when he described what all could happen. He said it better than anyone, even our own expert. All the horrible things that can happen when you have something in your heart that's a piece of metal, where you're one breath away, you know, from even sudden death. One breath away from it causing a clot in your heart.

You know, the thing that she had put in her to prevent her from having clots was now in her heart where a clot could form, according to Dr. Ciavarella, and migrate to your brain. Migrate to other parts of your body.

Now, I know that didn't happen, but it doesn't change the fact that this dangerous product that this company knew was dangerous, that they knew needed to be fixed, that they actually thought they had a fix in place and didn't tell her or anyone else about it, left it on the market after Dr. Kandarpa, who was the only one who saw patients in a clinical trial, thought they should stop, maybe reevaluate this thing and not sell it.

You know, she has this thing in her heart for three months; June, July, August. And you heard the story about her and her husband driving to Stanford. Her having to write a good-bye letter to her children and her husband. And I know that seems like, okay, but, I mean, I just -- just the terror and the horror that she must have been going through at that time.

Not knowing whether or not the only doctor that she could find on the internet that could take this thing out of her heart and her -- and out of her vena cava, you know, was in Stanford, and she didn't -- you know, she wanted -- I'm sure she wanted to fly to get there as fast as she could. They had to drive. And they had to drive and at night wondering whether or not that was her last night.

And, you know, and we put on an expert who -- and you have those numbers about how she needs to be monitored over the next -- the remainder of her life. And that totaled, I think I saw you write it all down, as $226,439.

Well, do we know what's going to happen to her over the next 40 years, whatever the life cycle -- her life expectancy is? No. But Bard should know. They should study these things and find out -- you know, do a registry. Have people come in and find out, what are the risks of us having caused a -- put a hole in your heart and causing scarring in your heart?

Maybe ten years later, what happens to people? We don't know. Well, we know that there's the potential that it could lead to problems.

At the very least, allow her to go to a doctor and have Bard pay for that to see if those things might happen as a result of her heart having been scarred by this device.

I'm getting there.

Okay. You saw the pictures. And here's the other thing, too. I'm only going to touch on this briefly, but you saw enough of this.

I don't know if these things work. I really don't. All's I know is that the testimony and the scientific evidence suggests that they don't. But doctors are still putting them in because theoretically they might.

And I'm not faulting her doctor. No one is. But if you're going to have a device that you don't even know works because you haven't studied whether or not it works, you are at the highest possible level of duty and obligation to the American consuming public to make sure that you've taken every step to design every potential risk out of that.

Now, no device is risk-free. We agree with that. But if you know your device has design problems that are increasing that risk, there is just no excuse for you to keep that device on the market when you know there are safer alternatives that you've already seen in your own engineering department and safer alternatives in the market.

All right. One last thought before I sit down. I want to leave Mr. O'Connor a little bit of time to -- for his rebuttal.

And that is, when you -- when you deliberate, I want you to think about the message that you want your verdict to have, not only for Bard but for just corporations that make

products.

I think that you want them to make different choices than they made. You want them to do something different than they did. You don't want people to be experiments in your effort to have a product and maintain a competitive advantage. You want to make sure they're well tested, that you do the clinical trial that you promised Dr. Asch you would do. You do the clinical trial that Dr. Kandarpa thought you should do.

And, you know, I suggest to you that when Bard gets up here and they -- Mr. Rogers is going to get up here in a second. I only ask this, that he talk about the facts in this case. He talks about the design and the choices his company made. And he talks about the evidence that came into this case, not through anyone else but his own experts and his own client's witnesses.

Ladies and gentlemen, thank you for your time. I appreciate your attention. I know you have a task ahead of you, and I know that you'll fulfill that task and that you'll follow the law and you'll apply the facts of this case to that law.

Thank you, Your Honor.

THE COURT: All right. Thanks, Mr. Lopez.

Members of the jury, we're going to take our 15-minute break. We will resume at 3:10.

Please remember not to discuss the case yet, and we'll

see you in 15 minutes.

(Jury not present.)

THE COURT: All right. Defense counsel, that argument took 1 hour and 4 minutes, so you have 15 minutes remaining for your argument and punitives case.

We'll see you in 15 minutes.

MR. ROGERS: Plaintiffs' counsel.

THE COURT: Oh, yes. I'm sorry. Plaintiffs' counsel.

All right. See you at 3:10.

(Recess taken, 2:54 p.m. to 3:09 p.m.)

(Jury present.)

THE COURT: Mr. Rogers, you may proceed.

MR. ROGERS: Thank you, Your Honor.

May it please the Court and ladies and gentlemen of the jury, I first want to, on behalf of myself and Ms. Helm and Mr. Condo and Ms. Camarata from C.R. Bard, and all the people of C.R. Bard, I first want to thank you for your time and attention.

I think that one thing that Mr. Lopez and I enthusiastically agree about is that you are one of the most attentive juries that I have ever seen. And I agree with him that I've never seen such furious and dedicated note-taking from a jury before. I can't imagine that something was said in this courtroom that you guys have not recorded in some fashion.

But, you know, when we first got together some two and

a half weeks ago, you know, I asked you to listen to the whole story. And I thought that when you did hear the whole story, that you would agree with me that Bard stands wrongly accused in this case.

And today, after hearing all the evidence for two and a half weeks, I believe that more than ever. And I want to tell you why.

But first we're going to do a few things. You know, when we first got together, I told you the key issue in this case was a risk-benefit analysis. And that's still correct. And I'm going to get to that in a moment.

But there are some things that I want to kind of get out of the way first that I think have been somewhat kind of distractions in the case. And I want to talk to you about what is not at issue.

And Mr. Lopez completely correctly anticipated that I was going to tell you that the Recovery filter is not an issue in this case. This is the first generation retrievable filter that Bard put on the market. It was on the market from 2002 to 2005, so it was gone for six years before Mrs. Hyde ever received a filter.

And we have spent a lot of time throughout the course of this trial talking about the Recovery filter. And you may recall when we first got together, when I gave the opening statement, that I told you that if we do spend a lot of time in

this case talking about the Recovery filter, ask yourself why. Why are we talking about that filter? And I expect you to draw your own conclusions.

But we saw witnesses throughout this case, mostly by videotape. We saw one live witness, Mr. Tessmer, regarding the Recovery filter. That's all those folks had to talk about. We saw many documents throughout the case that deal with the Recovery filter.

So if you see documents during your deliberations from 2005, 2004, these are usually Recovery filter documents. And I submit to you that that's not the filter that's at issue in this case.

And I next want to talk about a phenomenon that I think we've seen, and that is what I'm going to call the real world versus the litigation bubble. You know, we all have got lives, and when we're out there doing things, I mean, that's the real world. And I think that we all have our common sense, and we apply things as we move throughout our day-to-day decisions.

But I submit to you, ladies and gentlemen of the jury, that what we've seen in this case, a lot of it are things that exist only in what I will call the litigation bubble. They're things that are only here because we're in a case involved in litigation.

And to give you some examples of that -- and these are

other things I'm going to try to get rid of. You know, we spent an inordinate amount of time on some Bard documents, and specifically, I want to talk to you about two right away. And these would be the Bard documents that I would say that we have seen the majority of the time in the case.

And the first one that you may recall is called the G2 and G2X Fracture Analysis. Now, you didn't probably see this a whole lot, maybe you saw it some, but as you can see, the numbers are all in there. At this point in time, there had been sales of a hundred thousand filters, G2 or G2X filters. And you see at the bottom there, only two of the G2X filters contained in that number have experienced a fracture.

But more importantly, there were only 56 of these filters that had experienced a fracture out of that hundred thousand. And you can see for yourself that the rate at which Bard was seeing these fractures was .06 percent. That's not a number that we really spent a whole lot of time on, but that means that out of 10,000 filters, only 6 would have had reports of fractures.

Now, you heard Mr. Lopez talk a lot about Type A and Type B fractures, and he flashed this up on the screen. And this is the page you've probably seen regarding this document more than any others in this particular document.

And down at the bottom, we've got these numbers that are percentages. And these percentages were represented to you

to mean that the G2 filter performed more poorly than the Recovery filter, which Mr. Lopez claims is the most dangerous filter on the market.

But let's look at what that really means. I mean, those percentages that were laid out -- and Mr. Modra explained this, that these are percentages of .06 percent. That's what we're talking about. Not that 14 percent of the G2 filters on the market experienced caudal migration, but that 14 percent of the filters that had fractured, the 0.6 percent, also had caudal migration.

And if you do the math on this, this means that .0084 at -- as part of this analysis, G2 or G2X filters had experienced both a fracture and caudal migration at the same time.

And, ladies and gentlemen of the jury, that means that 8 out of 100,000 filters would have experienced those two failure modalities. And I think that's a very different representation than what you have gotten from plaintiffs' counsel.

Next, we saw this document probably more than any other. And this document has got a word that the plaintiffs like in it a lot, and that is the word that says "unacceptable." And we've heard it over and over again.

But, again, we didn't spend as much time on this portion of the document. And this is an analysis of caudal

migration, and this is what was the signal to Bard that there may be something you need to go investigate.

And importantly, if you look at the numbers again, out of about 9,000 filters that were sold, there were only 13 filters that had experienced caudal migration that set off this, you know, signal to go investigate.

And that gives us a rate of .15 percent. Again, you have got 15 -- that means 15 filters out of 10,000 would have experienced this particular issue so that you needed to go look into it.

And what happened? Well, we saw a whole lot of things that happened as a result of this number and this particular signal. Bard did a failure investigation report, a health hazard evaluation. They convened a panel of physicians, flew them all into Chicago. This is over ten doctors that came in to talk about this issue.

They also did a risk-benefit analysis and then provided FDA plenty of information about what was going on. And that's all because there were 13 reports out of close to 9,000 filters for caudal migration. And I submit to you that that is proactive activity of a company trying to make sure that everything with their product is okay.

And you heard Mr. Modra explain to you why. They try to set rates so that you get signals very, very early. It's a very conservative notion to take, that you get the information

that you need as soon as possible so that you can investigate as soon as possible.

All right. I also want to talk some more about the litigation bubble, and I -- since it's football season, I have to use a football analogy. And I want to talk about Monday morning quarterbacks. And I expect that y'all can look at me and tell that I didn't have a big football career, but that does not stop me, you know, after the game from criticizing the decisions that the real players on the field made.

And I will submit to you that the experts that the plaintiffs have presented to you fall into that category. And let's take a look at them one by one.

First we've got Dr. McMeeking. He has never designed an IVC filter. He's never tested an IVC filter. He has done nothing to bring a real filter in the real world to the market. But yet he comes in and criticizes Bard about their testing and how they've designed their filters. And, importantly, he's also doing the same thing in a completely different litigation against a different filter manufacturer.

We also saw Dr. Parisian. Dr. Parisian spent four years at the FDA more than 20 years ago. And since then, she has had a very lucrative career testifying against drug companies and medical product companies. And I submit to you that she is a career advocate for individuals like the plaintiff in this case, and that's what she makes a living

doing.

We saw Dr. Betensky. I agree with Mr. Lopez. She is incredibly well qualified. She is a statistician. And yet she did exactly what plaintiffs' counsel asked her to do, and that is to do this retrospective statistical analysis comparing the Bard retrievable filters to the Simon Nitinol filters. And then she compared those two things and came up what she called like a risk reporting ratio or something like that.

And, again, I will submit to you, that is not real world data. I mean, this is somebody carrying out and executing specific instructions on what to do in litigation.

And notably, she's also doing the same thing in the Cook litigation, so she's also involved in litigation against a different manufacturer. And she's also offered opinions about the DFMEA that Bard did, but she didn't even know what one was. So I suggest to you, again, what we're seeing are things that only exist in the litigation bubble.

Next we have Dr. Muehrcke, and he is certainly a qualified cardiothoracic surgeon. But Dr. Muehrcke also has advertised his services as an expert witness. You heard him say that he went and attended a class that lasted eight hours in Chicago to learn how to be an expert witness. And more importantly, he's offering opinions after looking -- or arrived at his opinions after looking at only a very small number of Bard documents.

But I think more than anything, he came into court and offered opinions about the cardiac status, the heart status of the plaintiff. But he had not looked at the majority of the records that relate to her cardiac health. He had looked at the records from the implant of the filter and the explant of the filter.

And I don't know if you remember this, but when I was asking him about the records from the plaintiff's visit to a cardiologist, he said, "Well, you have me at a disadvantage because I've never seen this. This is all new."

And I submit to you that doctors in the real world don't look at company documents. They look at medical records. They look at test results. They look at x-rays and imaging, and they don't look at company documents. But yet Dr. Muehrcke gave you his opinion based on hardly any medical records or medical information whatsoever.

Now, we also had Dr. Hurst, who also advertises his services as an expert witness. And he's never published on IVC filters. He still uses Bard IVC filters. As a matter of fact, he said two or three -- three or four weeks ago, he put one in. And he's going to come in and criticize Bard and their filters and tell you that something's wrong with them, but yet he continues to use them in his own clinical practice. And he also did not review all of the records that relate to the plaintiff.

All right. Stable. Mr. Lopez touched on this, and we've heard some of this, that the Bard filters are somehow not stable. And I want you to ask yourselves, you know, what does that mean?

You know, Dr. Muehrcke described it as falling back, kind of, and we heard several different descriptions of this. But I think you were intended to get the impression that once these filters go in, they move all around.

Well, first of all, I want to point out that both Dr. Hurst and Dr. Muehrcke both agree that all filters fracture. I mean, this is not something that is limited to Bard. But yet I think you were asked to believe that the Bard filters experience tilt, caudal migration, and perforation and that there's some interrelationship between those things that lead Bard filters to fracture more than other manufactures.

But you also heard from Dr. Grassi, our expert, who wrote the SIR guidelines, that yeah, he's heard that theory, but he's not aware of any medical literature that bears that out.

And I think the more important thing to ask yourselves, too, is how does it relate to this particular case and the evidence you've heard. And did the plaintiff's filter experience these failure modalities that the plaintiffs have focused so much about.

And, you know, when we started, I asked you to be

medical detectives, and I think you have done a very good job of that because I see you furiously writing things down when records and things are up there.

But I want to review some of those things, and first let's talk about tilt. And this is probably hard to see. Maybe you can see it better on your screen, but you'll have it back in the jury room.

But these are three images that I talked to Dr. Hurst about. And you might remember, these are images from CT scans from 2011, 2013, and 2014. And you might recall that if you see the tip of that filter, the very top of it, in the center of the cava, then the filter is not tilted.

And he agreed that this looks like a pretty well-centered filter, so this filter is not tilting. But what did he tell you? He said it's a very slight tilt of somewhere between 2 and 4 percent. I mean, it's very minimal.

But when I asked him if he had ever included in a report in his clinic on a real live patient that he's examining or looking at the images of, has he ever put any information in a report that would say that he sees tilt of less than 15 percent, and he said no.

So I submit to you that that is litigation bubble testimony that you're hearing in this courtroom that does not exist in the real world.

All right. Migration. We also heard about that. And

you might recall that Dr. Morris put these two slides up that showed the position of the filter when it was implanted and then the position of the filter right before it was explanted. And it's probably hard to see in that particular screen.

But Dr. Hurst testified that this was 5 millimeters of migration that he perceived. And to give you some sense of 5 millimeters, that's about as long as a grain of rice. And he said himself that this was not the predominant issue. But yet plaintiffs are trying to suggest to you that these things all work together to cause fracture.

Now, you heard from Dr. Morris that in the SIR world, the Society of Interventional Radiologists, that they don't consider there to be migration unless it's more than 2 centimeters. Because perceived differences that you might see on an image of where a filter is can be accounted for by something called parallax, that's just differences in the imaging; hydration of the patient can change how much the patient's cava is either swollen out or shrunken in; and then this -- literally breathing in and out can move the position of the cava up and down as much as 5 millimeters.

And the FDA has also acknowledged this issue with migration. And on the left-hand side, you see the document from FDA. That's their internal memo where they down-classified IVC filters. And on the right-hand side is from the guidance document that you saw that FDA issued about

IVC filters.

And as you can see, both of those documents state that caudal migration, number one, is usually clinically insignificant; and, number two, can be accounted for by these things that Dr. Morris described for you in the courtroom.

So I submit to you, again, this is things that we're seeing in the litigation bubble world that don't exist in the real world. And as Dr. Morris told you, this is something that just is not even clinically significant.

All right. Let's talk about perforation. And you might recall Dr. Morris went through some images with you where he kind of scrolled up and down just like you would if you're sitting in the hospital and looking at a CT scan, and he talked to you about perforation.

And he talked to you about how that's something you see, but sometimes there is this thing called tenting that might look like a filter strut is perforating or outside of the caval wall, but it's really not. And he informed you that he sees this kind of thing that we see in the plaintiff's CT image fairly routinely and that this is not something that he would believe is clinically significant, and he sees it in all sorts of filters.

Now, you saw this image in plaintiffs' closing argument. And this is the image or one of the images that Dr. Hurst used, but it was the main one that he wanted you to

see where he was going to tell you that the strut of the filter was interacting with the spine. But when I asked him about whether or not he had done something with his own computer to change this image so that he could bring it to court, he agreed.

And so, again, I submit to you that this is not real world things that you're seeing, that you're seeing things that are contained in the litigation bubble, and any perforation that happened was completely clinically insignificant.

All right. And let's look at the real world. You know, we had real doctors that were reviewing these CT images that the plaintiff had for various reasons. And you'll see that when they were reviewing these images, the real doctors that reviewed these wrote things like "IVC filter is identified." "There is a caval filter."

But these doctors did not note anything about perforation, tilt, migration, until the one doctor saw the strut that was in the heart of the plaintiff in an incidental finding. But these other failure modalities were not recorded in any of the treaters' records.

All right. G2X or Eclipse? Mr. Lopez wants me just to admit that this is a G2X. And when I started with you a couple of weeks ago, you know, I told you that I don't think we know. And I still believe that today. I don't think there's any evidence that you have seen where anybody can say, yes,

this is a G2X filter or an Eclipse filter.

But very briefly, Dr. Kuo did call both -- he used both the words "Eclipse" and "G2X" when he looked -- you know, in his records. And in his testimony, I don't think he said anything that would -- that could possibly be used to say, well, gee, I saw this filter and it was a G2X filter.

If you see on the left-hand side, he is saying that according to the imaging, I can't tell. I mean, these two filters look just alike on imaging.

And on that right-hand side, you know, he is again talking about an image where he says G2X. And he's -- and specifically, if we go back in this particular thing, that same word, "spot radiograph" -- do you folks see that? You know, he's getting asked about that particular image in this right-hand piece of testimony, the spot radiograph.

So he's talking about an x-ray. And he said, yeah, G2X, because that's what that particular note of his about the spot radiograph said. But you can see on the left-hand side that he clearly says that when you look at this on imaging, you can't tell.

But Mr. Lopez also correctly predicted that I was going to show you some invoice records, because I think that's probably the best evidence we have about this. And as you can see, and if you might recall, the plaintiff had a jugular approach with her filter. And the last G2X that was sold to

this hospital with a jugular delivery kit was sold over a year before her procedure.

And then if you look down, February '11, the month her procedure was, there was a jugular kit that was sold to the hospital. And with the invoices, we saw that this was shipped out of Bard on February the 23rd for two-day delivery to the hospital, and it arrived on February the 25th, the day of her procedure.

And as we saw from the notes in the records, and I went through these with Dr. Hurst, that if you look at these -- the monitoring for the critical symptoms, that this procedure started around 1:00 o'clock, which I submit to you gives plenty of time for this filter to arrive and be used in the OR by 1:00 o'clock.

But as I told you in the opening, I don't know that this really matters. Again, I don't think we know if it's a G2X or an Eclipse. And I think the more important thing is that it's Bard's position that both of those filters are safe and effective filters.

And I think it's borne out by these rates that you've seen several times that Bard is constantly tracking and monitoring and keeping up with the reports that come in from doctors, hospitals, competitors, wherever. And they put these things into these rates where they calculate the sales versus the reports and they track and trend that.

And I submit to you it's always less than 1 percent. And, again, I told you at the beginning and I'll tell you again now, these rates are not perfect. We know that there is some level of events that happen that do not get reported. But it's the best information that Bard has, and it's a big piece of their story.

Okay. I'm finally going to get to risk-benefit. And first I want to talk to you about the allegations in this case or the claims. And these are the things that the plaintiff has the burden of proof on.

We have a claim for a design defect, causation, and damages.

And the first thing I want to do is point your attention to a jury charge that you're going to receive. And you've already been charged, but I think you'll get a printed copy of these.

But for each claim, the burden is on the plaintiff to satisfy you by the greater weight of the credible evidence to a reasonable certainty. That is the burden that the plaintiffs have to satisfy in order to recover in this case.

Now, there's two claims. They're both design defect claims. One is strict liability and the other is negligence. I'm going to talk about both.

But first I'm going to get you to look at the charge on strict liability. And we're going to focus now on this

first portion of it, and it reads: The filter is defective because the foreseeable risks of harm posed by the filter's design could have been reduced or avoided by the adoption of a reasonable alternative design by Bard.

And so that's a requirement that the plaintiffs have to prove to you that there was a reasonable alternative design.

But, this is very important, there is an "and" in this portion of the Wisconsin law that is being applied to this state -- or to this case. And so you don't just get to recover if you just have a reasonable alternative design. You've also got to prove that the omission of the alternative design renders the product not reasonably safe.

And the first thing I'm going to focus on about strict liability is that part, "not reasonably safe." But let's take a look at the negligence part as well.

And under the negligence standard that you're being charged for design defect, the plaintiff has to prove that there was an unreasonable risk of injury or damage. So to put those two things together, not reasonably safe and unreasonable risk of injury or damage, if you look at both of those things, it's a reasonable -- reasonableness standard which leads us to the key question: Did the benefits of the Bard G2X or Eclipse filter outweigh the risk? That is what is up for you to decide.

Now, let's talk about benefits first. And I think you

saw a lot of evidence about this, and this is the Surgeon General's Call to Action from 2008. And as you can see, the Surgeon General identified that DVT and PE is the cause of as many deaths in this country as car accidents, AIDS, and breast cancer.

And you also saw that the Surgeon General has identified what the Surgeon General believes to be treatment modalities for DVT and the prevention of PE; and specifically, the Surgeon General identified anticoagulant medication and, as you see here, IVC filters.

All right. And let's think about this in regard to the plaintiff. And I think you have heard plenty of this, but I think everybody understands that at the time that the plaintiff received her filter, she had experienced three DVTs and this is her second PE. And she also got diagnosed with a clotting disorder called a protein C deficiency, which will require anticoagulation for life.

And Dr. Morris went over this film with you, which was the CT scan of the PE itself. And you might recall that that right-hand side, on your right part of your screen, that right lung had this very large PE, that gray area where you see that the blood flow is cut off from the rest of the lung, the lower lung. That was the PE that the plaintiff experienced.

Now, every medical witness that you heard in this case who talked specifically about the plaintiff agreed that she

needed a filter. And specifically, you heard about more benefits than that, than just getting the filter.

But Dr. Morris told you that there is close to a one-third risk of death from a recurrent PE. And Dr. Henry, the implanting doctor, said that he wanted to add the IVC filter as an additional benefit for the plaintiff, a belt-and-suspenders kind of approach, because she had already started anticoagulant, but he wanted to make sure that there was no risk for PE in that interim in case the anticoagulant was not effective.

And even Dr. Muehrcke agreed that a patient very well may not survive a second PE to their lung, particularly if it's a large one, and he even testified that he himself has seen Bard filters, not just any IVC filter, but Bard filters stop a clot to prevent a PE.

Okay. Another benefit I want to talk about is long-term retrievability. And you heard about some of this way back in opening statement, and not just my opening statement but plaintiffs' opening statement. And you heard that in the 1990, it was a different era. I completely agree with that. The only filters that were available were permanent filters.

And you also heard in opening statement for plaintiffs' counsel that there was this desire for retrievable filters. And that came from the medical community. It wasn't like Bard made that up. Doctors wanted this as a treatment

modality.

And you heard Dr. Morris say that that offered treatment options for patients who previously would not have had those treatment options. For patients that could not be anticoagulated on a longer term, you could put a filter in and leave it in for a long-term period.

And our IFU, which Mr. Lopez says doesn't have anything to do with the case, you know, does not have a specific length of time that the filter has to be retrieved. And that was a huge benefit for doctors who want to treat patients.

Now, I submit to you that this played out in this case. I mean, after the filter had been in the plaintiff for three and a half years, when Dr. Kuo went to retrieve it, he was able to do it in a procedure. I mean, from the time where they gained access to the jugular vein to remove the filter, it was about 18 minutes. So the filter came out just like it's supposed to, three and a half years after it had been indwelling.

All right. Another benefit I want to talk to you about is the continuous improvement of the Bard IVC filter retrievable line. And you saw Mike Randall this morning talk to you about this particular demonstrative, how Bard has worked over the course of years to try to improve the filters, that they continue to try and make them better and learn from

experience.

And he even told you about some stuff that didn't work. I mean, the G3 and the Platinum. Those were ideas that they tried to build prototypes and test, and ultimately they were determined to not work. And sometimes that happens. And so this stuff doesn't happen overnight. It's an iterative process that happens over time, and it takes time and a lot of hard work.

All right. Testing. And this is, again, a benefit. And you've probably seen more about filter testing than you ever cared to see, and I'm not going to bore you with a whole lot of it.

But we did see the FDA guidance that tells IVC filter manufacturers, these are the types of tests that we want to see when you submit your applications to us. And Bard did submit those things, and this is for the G2 filter, but they also submitted more types of tests than what the FDA asked for, including performing a clinical trial, the EVEREST study, which plaintiffs are very critical of and say it was a retrievability-only study.

Well, that was certainly one of the purposes of that study, to determine if the filter could be safely retrieved within a six-month period of time.

But as you can see from this document that we talked about with, I believe, Shari Allen O'Quinn, that, you know, a

secondary endpoint for the EVEREST study was to collect safety data. And, you know, a study can be for more than one purpose. I mean, you can gather data about safety while you're doing a study at the same time.

And so I submit to you that Bard did do a clinical study that did demonstrate safety and efficacy of the G2 filter.

All right. This was also borne out on the bench in the testing, and you folks have heard probably -- like I said, you've had about a gutful of this stuff, but it did demonstrate more fracture resistance of the G2.

And then we move to the G2X. More bench testing there. The G2X was carried out to 77 years before failure.

And then we move to the Eclipse where electropolishing is added. You heard about that from Mr. Randall today. And, again, you heard about the various tests that were performed on that filter.

And the bench testing, again, continues to bear out that these filters are getting better and better as iterations of the filters come into the design world.

Dr. Briant, this is another kind of litigation bubble/real world thing. You know, he is a retained expert of ours, but, you know, when he testified, in his enthusiasm for science, I mean, he talked about the real world things that Dr. McMeeking did not take into account when he did his testing

and that the tests that Dr. McMeeking did, the kind of theoretical tests, did things that the human body was really not even capable of doing.

So, again, I submit to you that's real world testing versus litigation bubble testing.

And Dr. McMeeking also talked about some things to suggest to you what would be alternative designs, safety features that could be added to the filter. And he specifically mentioned caudal anchors, perforation limiters, and a smoother neck.

But if you were listening -- and I'm sure you were, and probably taking notes, too -- you know, these, he said, were ideas. I mean, there's been no real world testing of any of his ideas.

And if you remember kind of the product life cycle that Mr. Carr talked to you about, yeah, ideas are good and that's where they start. But then you've got a concept phase, a feasibility phase, a development phase. All of that has to happen before you can launch a product.

And I submit to you that Dr. McMeeking is stuck in an idea phase, and the Bard engineers who are doing this in the real world and not the litigation bubble are doing these things day to day. Every day they get up and go to work, and they're not Monday morning quarterbacking and criticizing decisions and testing what somebody did in the real world.

Okay. Risks. I told you at the beginning that these products have risks. There's no question about that. Every witness who has testified, every expert has told you that, yes, all filters have complications. We all agree with that.

And you saw a lot about this document. And this is an internal Bard document that analyzes MAUDE data. And you might recall that MAUDE data is the internal FDA database where everybody submits all their information to, but it's completely public. You can go on a website and search within it. You can look up to see what products have had what reports. But that's what it is, it's reports.

And Bard was analyzing this data internally. And Mr. Lopez wants you to believe that this is where the deepest, darkest secrets were held and that they didn't compare -- when they did this report, you know, they didn't use the Simon Nitinol filter. He acts like that's really, really bad.

But I submit to you that if you're doing your deepest, darkest secrets, you know, wouldn't you put everything in there? I don't really understand why the fact that the Simon Nitinol is not in here is such a big deal.

But I submit to you that the more important thing is, as we saw from the FDA website itself, that the MAUDE data, because it comes from all kinds of different places -- and manufacturers use perhaps different standards on how they report. And the FDA itself says right there on the cover page

of the MAUDE database that this data cannot be used to compare rates of problems between products.

Now, so I'll let you ask yourself: So is it a good thing or bad thing that Bard's looking at this data and analyzing it? And I submit to you that's something that's a good thing, I mean, that they're looking at it and they're trying to figure out, can we improve? And where do we stand?

And you heard John Van Vleet say, who has worked at many different medical device companies, that he's never seen a company that has a more conservative approach to reporting than does C.R. Bard.

And so, again, we have no evidence in this case whatsoever how any of the other companies that the plaintiffs are asking you to compare Bard to in this MAUDE data, which FDA says you can't do, but we have no evidence how they report data. I mean, we don't know what standards they use. We don't know how frequently they report. So all of that is just guesswork. And so I submit to you, that is not some evidence of something really bad going on in this case. Because MAUDE data is unreliable.

And the more important thing, again, is the numbers that Bard tracks and trends continuously and constantly. And again, to look at those numbers in a little bit different way, as far as reports to Bard of certain types of complications, with the G2X, with fracture, migration, and tilt, it is over

99 percent of those filters receive no reports of that, and that's out of over 50,000 filters that were sold.

And for the Eclipse filter, the numbers are even a little better. And that's out of 66,000 filters that were sold.

All right. Let's talk a little bit more about reasonable alternative design, and I'm going to get back to this particular jury charge. And this is a requirement. I mean, the plaintiffs have got to prove a reasonable alternative design to you.

And we've heard about sort of different things, maybe different parts of different filters, but I think the ones that have been posited to you as being reasonable alternative designs are really these three filters: the Simon Nitinol, the OptEase, and the Meridian.

And we'll start with the Simon Nitinol. Simon Nitinol was cleared for use in 1990. And that was the time where, you know, videotapes were -- you know, that's how we watched movies, were videotapes in 1990. We had disposable cameras. We had phones that were the large portable phone you could walk around in your house with an antenna that you see Jerry Seinfeld still in reruns using on that show.

But that was the '90s. That was a completely different era, like you were told in openings by plaintiffs' counsel. And this filter is just not a viable option, because

as I'm sure you've heard over and over again, this is a permanent-only filter.

So I ask you to ask yourselves, how can a permanent-only filter be an alternative design for a filter that is intended to be retrieved? It makes absolutely no sense to me.

All right. But more importantly, we saw from Dr. Henry's records and his testimony that he wanted a retrievable filter. And so a permanent-only filter is not the product that he was looking for.

And even Dr. McMeeking agreed with that, that if it is a retrievable filter that the doctor wanted, the Simon Nitinol is not it.

And here's a piece of real world data. I mean, the filter, the Simon Nitinol filter that the plaintiffs are suggesting is a reasonable alternative design, is not even commercially viable. It is not available for sale in the United States today, and you saw this with Mr. Carr, how the sales of this filter have continued to trail off. And doctors just don't want to use it. It's just not something that anybody in the medical profession wants to pursue.

I think we've probably heard -- I'm going to switch to the OptEase now, and I think we've heard probably the least about that filter than any other. But that was suggested to you as a potential reasonable alternative design. It obviously

looks very different than the Bard filter.

But you heard Dr. Muehrcke say that he tried that filter out, and he didn't like it. And one of the big issues with this filter is it's just like an early generation retrievable filter. It can only stay in a patient for a very limited amount of time before it becomes a permanent filter.

And according to the labeling for it, Dr. Muehrcke agreed with me that it was only indicated for 14 to 23 days of indwell time in the patient, and then it's either removed or has to be left in. And so I submit to you that is not a reasonable alternative design.

And you also heard Mr. Carr and Mr. Randall this morning talk to you about how there's trade-offs in these designs. And with the OptEase filter, given its design, it is much more likely to cause an occlusion of the IVC, which is an issue that we really have not spent a lot of time on, but that's also a very dangerous potential complication of IVC filters.

All right. And lastly, in the category of no good deed goes unpunished, the plaintiffs suggest to you that the Meridian filter, the next generation that Bard came out on the market with, is also a reasonable alternative design. So plaintiffs want you to punish Bard for its continued iterations of developing these filters.

And as you might recall, the Meridian filter added

these caudal anchors to the filter. And that, as you heard, improved tilt and caudal migration. It made those numbers better.

But you heard from Dr. Hurst that tilt and caudal migration are not predominant issues in this case. And more importantly, this filter was not on the market in February of 2011, when Mrs. Hyde received her filter. It had not been cleared yet by the FDA. Dr. Parisian told you that meant if you'd sold it before that or used it, it would be adulterated and misbranded.

And it was still being tested. So this filter was not a viable option because it was not on the market and available to Dr. Henry in order to use.

And most importantly, this was a very interesting thing that we found out when Dr. Briant was testifying, that Dr. McMeeking, who has suggested to you that caudal anchors and perforation limiters, which are also -- been incorporated into the Denali filter, the current Bard filter that's on the market, that those are things that may have been something that would be a reasonable alternative design to incorporate into the Bard filter that's at issue in this case.

But what Dr. McMeeking did not tell you when he was on the stand was that he's also issued opinions that the Meridian filter and the Denali filter are not safe and effective and that they do not improve fracture, migration, perforation, or

tilt.

So I submit to you, ladies and gentlemen, if we had been in here and we had a Denali case, we'd have heard the same testimony from Dr. McMeeking. But because this is another case with a different filter, we didn't hear about this opinion.

Okay. Next up is this last part of the statute, which is critically important, that the reasonable alternative design that perhaps could have improved the product, the omission of that made it not reasonably safe.

And so I was thinking about this and trying to think about a way that might make sense. But to start off, I want to talk about Dr. Hurst. And he agreed with me that all IVC filters can be made safer. And that's what we've seen with this Bard line of products, iterations that add to and make them safer. And so that's a continuum that always is constantly happening, hopefully, or that's the good thing that should happen.

But so just because you can improve does not mean that the product is not reasonably safe. And so I started to think about my own household, and I have three daughters who are in college. And one of them has the dubious distinction to have been voted by her senior class, for senior superlatives, most likely to cause a car accident given the number of at-fault accidents that she had had while she was in high school.

And so in our household, we have got multiple cars

and -- because we've got five drivers. And we only have one car, my wife's car, that has got these blind spot alerts. You know, they're incorporated with sensors in your rearview mirror, and so that is a safety feature of a car.

Mr. Lopez talked about cars, so I'm going to get into that a little bit too.

But so that's something that would make a car safer, and so that's a good thing. But I don't think that that means that the other cars that we have in our driveway are not reasonably safe. I mean, those are -- that's good to make those things happen, but it doesn't mean that the cars -- the Camry and the Honda Accord that my daughters drive, it doesn't make those cars not reasonably safe.

It's an additional feature, but it doesn't render the ones that don't have that feature something that's defective. And that's what you're being asked to do in this case.

Okay. Let's talk about weighing these risks and benefits. First of all, I submit the FDA's done this in some respects when the FDA down-classified filters. You saw some of this. You know, the FDA looked at what the potential risks were, and they identified that the risks of IVC filters were potentially even life threatening but so was the disease that they're trying to cure or trying to prevent.

And they looked at the rates that were in the published literature and identified various things for all

these failure modalities, and then they determined that even though there are those risks, that the benefits outweighed those risks, and they down-classified filters from Class III to Class II so that they could be -- go through the 510(k) process, which doesn't require as much regulation as a product that goes through the PMA process. Sorry, that's getting technical.

All right. But let's look at what the history is, though, with FDA. You know, after the down-classification, which happened in 1996, FDA issued that guidance document on IVC filters. And since then, there have been multiple clearances of Bard products.

And you heard Dr. Tillman, our FDA expert, who was there for 17 years and was the head of the office that looks at 510(k) applications, tell you that even though there is a comparative standard for a 510(k) application, you're comparing a new product to a product that's already on the market, but it's still considered safety and efficacy. That doesn't just go out the window.

And Dr. Parisian, I think, wanted you to believe that FDA was just an inept organization that is an honor system. It's the manufacturers that have all the information, and that FDA really doesn't do anything except just bumble around and rubber stamp things when they come in. But I think you got a different view of the world when Dr. Tillman testified that the

FDA is a real organization that does its job in a very dedicated fashion.

Okay. This is another part of the strict liability statute that I want to discuss. And this is -- you're going to be charged on this as well. And -- or you have been charged, but it will be in what you receive in the jury room.

But this is the inherent characteristic part of the Wisconsin law. And it reads: The plaintiffs may not recover on their strict liability claim if the damage was caused by an inherent characteristic of the product that would be recognized by an ordinary person with ordinary knowledge common to the community that uses or consumes the product.

And so I suggest to you that the community that uses or consumes the product are doctors. They're the people who know these products, and they're the ones that know about them. And we saw a lot of evidence about what the community of users of doctors of these products know.

And very briefly, we saw the SIR guidelines. You saw Dr. Grassi testify about how they compiled these. And they searched the world literature and tried to come up with what were the ranges of complications that you see with filters. And that was published in the medical literature.

And Bard has never taken the position, contrary to what Mr. Lopez says, that the SIR guidelines, as long as you're within that, you're okay. That's not what Bard's position is.

But this is an important piece of data of what doctors would know about IVC filters, and it relates to the whole community of knowledge, and it relates specifically to this portion of the statute that you've been charged on.

And what else did we see? The EVEREST study. It was also published in the medical literature. And so this is not information that Bard is trying to hide or cover up. All the complication rates that appear in the EVEREST study were published in the peer-reviewed literature for every doctor to see.

And you also saw this little document, which was a -- what they call a placemat, something that was laminated for people who are sales representatives when they call on doctors to hand out. And you might recall the Nicholson study that Mr. Lopez questioned various witnesses about and how it showed really high rates of complications with Bard filters.

But Bard put that information about the Nicholson study in this document, in this little place card, to hand out to doctors. So this information was not covered up or swept under the rug.

The 2010 FDA notification, that's another thing that doctors would have known and seen. And as you can see, this was a few months before the plaintiff received her filter. And this notification was directed toward doctors who are likely to either put in IVC filters or care for patients who might have

an IVC filter.

And as you can see, they specifically pointed out that the known risks included fracture, penetration, and migration of filters. All of this information was known to the community of doctors who used these products.

And you heard Dr. Morris say specifically that once that public health notification came out, that that was something that was well known in the medical community. And he agreed that that was something that the community of doctors who used these products were aware of.

And it was also in the IFU. This is the Eclipse IFU, but it was in the G2X IFU as well. And so all of these various complications were included and warned of. And as you can see, we've got movement, migration, fracture, including the potential removal of a fragment that's in there, as is perforation and tilt.

All of that information, you can look at yourself when you get to the jury room. It's in the IFU for both the G2X and the Eclipse filter.

But, you know, there's also this statement, that -- I think every doctor knows this already, but it's part of the Bard labeling. But you've got to consider the risk-benefit for every single person. You've got to decide the risk that that person is under given their potential risk of a deadly PE versus the risks that come with the filter. You have to weigh

that and make individual decisions.

And IFU also points out that the standards for the Society of Interventional Radiologists suggest that patients should be routinely followed once they have an IVC filter. And that's information that was known to the medical community through this IFU.

And Bard didn't stop there. You saw this, the patient brochure that was cleared through the FDA. And it contained something in more layman terms that doctors could give to patients if they chose to. But it informed patients, if they were to get this from their doctor, that the entire filter or pieces of the filter may break loose and travel to the heart or lungs, causing injury or death. You may need to have additional surgery to retrieve the filter or pieces if they break loose.

That was information that doctors -- that Bard made available to doctors, who could make that available to their patients.

All right. So in the verdict form, this is what it's going to look like. And you're going to have to answer specific questions.

And the first one you're going to have to answer is: Do you find by the greater weight of the evidence, to a reasonable certainty, that Bard is liable to Mrs. Hyde on the strict product liability design defect claim?

And I submit to you that the answer to that, based on the risk-benefit information you've seen and based on what was known to the community of users of IVC filters, that that answer is no.

All right. Now we need to move on to negligence. This will go a lot faster, I promise. But here's the charge. And I can't see it over there, so let me find it.

It's a rather long charge, but what I am going to focus on -- and you're obviously going to be able to read all of this in the jury room -- is that it does require the plaintiff to prove that the manufacturer, in the exercise of ordinary care, did not use reasonable and adequate testing.

And I'm done with testing. I'm not going to go back over that for the most part. But I think our testing, we demonstrated to you, was reasonable and adequate. And you've also seen how this iterative process led to new generations of filters along the way.

You've heard a lot about long-term clinical studies, so I do need to talk about that. And, you know, exactly what is a long-term study? I mean, that's a kind of relative term.

But I think plaintiffs are suggesting to you that studies should be done that last 20 years, perhaps. And if that's the case, then when the plaintiff needed a filter in 2011, a study would have had to have been started and run for 20 years that would have had to start at least by sometime in

the early '90s for that filter to have gone through that whole long-term study as the plaintiffs describe it and then put the filter on the market.

So that would mean that by the time the plaintiff got her filter, probably the Simon Nitinol would be ready for the introduction to the marketplace in 2011. And as we've seen, that product is really kind of a dinosaur in the IVC filter world.

We've also heard evidence that there is no known IVC filter manufacturer, permanent or retrievable, that has done any study like what plaintiffs are arguing to you should have been done by Bard in this case. And you heard evidence that the Simon Nitinol filter, which is a permanent-only filter, Mr. Carr talked about this from his experience at NMT, that the study that was done for that filter, which was a permanent-only filter, lasted six months. I mean, that's how long they looked at patients, for six months.

And the EVEREST study, which the plaintiffs are very critical of as not showing anything about safety and efficacy, had that same endpoint of six months if a person stayed in the study that long and the filter remained in them that long.

So, again, I don't think this is real world things that we're talking about here that plaintiffs are suggesting that Bard should do. I mean, these are things that exist in the litigation bubble.

All right. EVEREST results, we'll talk about this very quickly. All this information, even though plaintiffs are critical of it, was shared with FDA. I mean, here's a pullout from the submission to the FDA about EVEREST when they were asking for clearance of the G2 filter as a retrievable filter. All of that data was included in the submission, and FDA cleared that submission.

But more importantly, in the Eclipse and the G2 filter, in the IFU, all the information about the EVEREST study is in the IFU. Doctors can read this and know about it. Again, this is not something that is being swept under the rug and something that portends that there is something terrible going on. This is clinical data that is in the IFU, and doctors can read it and analyze it for themselves.

We heard a lot about Dr. Kandarpa. He was the medical monitor for the EVEREST study. And as you may have heard, you know, he's been paid by plaintiffs' counsel to meet with them, and he also last placed an IVC filter in the early 2000s. He's never placed a retrievable filter. And he never told anybody at Bard that he thought that the G2 filter should be redesigned or that the EVEREST study should be stopped.

So as far as FDA communication is concerned, this is kind of my -- probably -- hopefully my last stop on negligence. You know, Bard provided a lot of testing and test protocols and test results to the FDA.

You know, Dr. Parisian said, you know, all the FDA gets is just summaries. I mean, it's very high-level stuff, and they just sort of rubber stamp it when it comes in.

But, you know, I think you saw over and over again that these submissions that Bard has made to FDA are quite large. And they included a lot of the actual protocols and a lot of very detailed information about the test results.

So I submit to you this is not something that's a rubber stamp by the FDA, and this is not evidence of a company that's been negligent in the way that it's gone about bringing its IVC filters to market.

And, specifically, I wanted to point this out. And this is a submission to FDA, and this relates back to the unacceptable document that we talked about when I first started and that we've seen so much air time about.

But FDA was given this information about that by Bard. Bard informed them that they had this signal and informed them that they were going to change the way they were looking at caudal migration versus cranial migration. At one point they were looked at all together, but they were going to break those out and look at them, and all of that was given to FDA. Again, this is not the things that a negligent company does.

So I submit to you that on the verdict form, the answer to was Bard negligent is no.

All right. Now I'm going to move into causation, and

hopefully I'll be wrapping up soon. But --

THE COURT: Mr. Rogers, you asked me to prompt you at one hour.

MR. ROGERS: Thank you, Your Honor. I appreciate that.

THE COURT: We're at one hour.

MR. ROGERS: But before I move into causation, I wanted to say something.

You know, I think that we've all had experiences where something happened two, three years ago and you feel like you have a very crystal-clear memory of it, and you think, yeah, this is exactly -- I have in my mind's eye exactly what happened, perhaps the way someone looked or something of that nature.

And then you see a picture several years later and you go, "Gah," I mean, how did that happen? Because my memory is obviously, you know, not 100 percent accurate, and I think that happens to all of us. And I think we filter things as we move along based on various experiences.

But as far as back pain and abdominal pain is concerned, you've heard about that, and that is the plaintiff's burden to prove to you from a causation standpoint, that the filter caused these things. And I don't doubt that the plaintiff genuinely believes that that's the case.

But as we saw from the records, there were a lot of

things going on during this time period that the filter was indwelling in the plaintiff. And we went over some of those things. But there was the -- you know, kidney stones, ovarian cysts, diverticulitis. All of those things were other issues that were occurring that I think perhaps account for the back pain and abdominal pain.

And we also saw this record that indicates that at one point when the plaintiff did go to a doctor who was a pain specialist, that back pain had been an issue for really quite some time, going back to 2007, well before the IVC filter was implanted.

I need to talk about chest pain and chest palpitations too. That's another claim that you've heard. And the record from Dr. Shehane -- "Shehane" -- I'm not exactly sure how he says it. But, you know, this is the record where after the strut was discovered in the heart, the plaintiff went to this cardiologist in Las Vegas for two visits.

And as you can see, his record indicates that the examination was benign and that the patient was essentially asymptomatic. And on the second visit -- and this is when the plaintiff reported to Dr. Shehane that she was going to go to Stanford and have the strut removed, that, you know, he said, "Call me if you experience any symptoms."

But one thing that I think is important, we didn't really see any complaints of chest pain until the strut was

discovered, and that's when that started. And I'm not suggesting that that was not a real perception, but I don't think that it happened until the plaintiff had knowledge that that -- that the strut was there.

And then as far as palpitations are concerned, you may recall this. Dr. Muehrcke agreed with me that based on imaging in 2013, a CT scan, that the filter had not fractured at that point. You can see all the struts, all 12 struts present and accounted for, you know, in this image. And that's probably awful small on your screen, but he agreed that at this point in time, in June of 2013, there was no fracture and there was no strut in the heart.

But yet on the left, we have a record from 2012 from Dr. Thummala, the plaintiff's hematologist, that indicates that she had complained at that point, almost really a year or more before, that she was experiencing palpitations.

Now, Dr. Muehrcke also talked to you about future issues and that the plaintiff may need to establish care with a cardiologist, that she would need an annual echocardiogram, annual EKG, and that these are things she needs for the rest of her life.

And I'll submit to you that these are litigation bubble things. For reasons that still are not clear to me, we heard that this care should happen in Wisconsin when the plaintiff lives in Las Vegas, some 1,800 miles away. So I'm

not exactly sure why the care needs to be in a completely different part of the country, but that's the evidence that we heard.

But more importantly, we heard from -- as far as the real world records, that it's been four years since the strut was removed, and there is no record, no evidence that the plaintiff has experienced any arrhythmia. There has been no visit to a cardiologist in that four-year time period.

There was an ER visit in 2016 where a cardiac exam was done. There was a nuclear stress test that was done, CT scan, EKG, and all of those things were normal, and the plaintiff was discharged with the diagnosis of reflux.

And we also saw that Dr. Kuo, in his testimony, told the plaintiff that she could return to normal activities.

We also heard from Dr. Poll. He's a practicing cardiologist at the University of Pennsylvania that he's been doing for years and years. And he reviewed all of the records, unlike Dr. Muehrcke, who only looked at very few. And he determined that essentially the plaintiff had normal heart function while the strut was in the heart, and then since then, she's also had a completely normal heart and that she requires no additional monitoring at this time.

So I also need to speak very briefly about damages. That is something that, again, the plaintiff has the burden of proof on. And it's something that if you jurors believe that

damages should be awarded, it's up to you. I will submit to you that I think that that would not be indicated in this case if you don't find for strict liability or negligence.

But if you do get into a discussion about damages, the only thing I'll say is that you need to be fair. I think the law even says you need to be fair to both sides. And it's up to you as jurors based on your common experiences and your real world experiences what you think that that's worth.

Punitive damages, I really don't even want to talk about this, but I need to because the standard is very different. You know, there's two different standards that are being applied in this case. For punitives there's a heightened standard. It requires clear and convincing evidence, whereas the other require -- just the liability claims require greater weight of the evidence. So this is a higher standard for punitive damages.

But I would submit to you that there really has been no evidence in this case to suggest that Bard should be liable for punitive damages. And I think that answer to that question is no.

And there's also the charge that specifically says that in order to find punitive damages, you have to find either malicious conduct or intentional disregard. And with intentional disregard, you have to find that the conduct was deliberate in actual disregard of the plaintiff's right to

safety, health, or life, and sufficiently aggravated to warrant punishment by punitive damages.

I submit to you that is a very high standard, and we have not seen evidence that comes close to an award for punitive damages.

And at the beginning of the case, I told you you were going to get to meet most of these folks, and you did. And it's up to you now to assess, based on your real world experiences, the conduct of these individuals.

So punitive damages, I submit to you, is a no.

Now, before I wrap up, I'm going to take us all the way back to the very, very beginning. And -- but you do need to understand, I'm going to sit down and Mr. O'Connor may have a chance to speak to you very briefly. But I don't get to respond to that. This is my last chance to talk to you.

And I'm sure you've figured out from watching sidebars and watching us in the courtroom, if you let us go back and forth, we'd be here for another three or four weeks. But anyway, I have to sit down after this.

But before I do, I do want to remind you of your oath, and this is the oath everyone took. Because it's very hard in life to say no to people, like you're being asked today. You're being asked to give an award of compensation to an individual, and that's sometimes difficult to just say no, that that's not the right thing to do, because we like to help

people.

But I want to remind you, at the beginning of this case, each one of you took this oath: Do each of you solemnly swear or affirm that you will well and truly try the matters in issue now on trial and render a true verdict according to the law and the evidence, so help you God?

And so your bounded duty is to apply the law and the evidence. And that means you cannot let emotions or sympathy or the desire to help people interfere with that.

And with that, I again suggest to you the risks and benefits in this case, when you take that into account, that that means that you should return a verdict for Bard. And I remind you again of these real world rates that Bard tracks and trends, and I ask you to use your real world experiences and analyze the evidence and apply the law and ask you to return a verdict for C.R. Bard.

Thank you.

THE COURT: All right. Thanks, Mr. Rogers.

Everybody, stand up for a minute.

Counsel, would you approach for just a minute, please.

(At sidebar on the record.)

THE COURT: It's just a question for Mr. O'Connor: Do you want me to give you prompts on any time?

MR. O'CONNOR: Yes. Give me 10 minutes, and I'm going to have to take a gamble. I think I have 20 minutes left.

THE COURT: You got 15.

MR. O'CONNOR: 15?

THE COURT: Yeah, there's 15 minutes left in your time.

MR. O'CONNOR: 10 minutes.

THE COURT: So give you a prompt at 10? Okay. There's what I'll do.

(End of discussion at sidebar.)

THE COURT: You can keep standing for just a minute, because we're not going to get out of here right at 4:30 today, but it's better to finish the argument so we're done for the day.

Mr. O'Connor?

MR. O'CONNOR: Thank you, Your Honor.

Well, good afternoon, and as you can probably tell by the clock, I have to be brief. But I want to talk to you about something that Mr. Rogers started talking about, about how this case and critical it was about the Simon Nitinol filter and the Recovery.

You know, those two filters are an inconvenient truth for the defense because they know without the Simon Nitinol filter, they don't ever get into what they tried to do in the retrievable market. Because that was the predicate device, and that would dictate substantial equivalence on all their devices, which the evidence has shown didn't occur.

Now, there's something else that I want you to think about, and that's the EVEREST study and what they keep telling you. What Bard learned in the EVEREST study was there was a relationship between those failures, tilt, perforation, fracture, and migration. And that was the purpose of the Venn diagram.

And that was the study where they realized they had to do something about it, and that is the study where it confirmed in their mind the need for caudal anchors, something that had been out there in the field of medical devices for quite a while. But it was then, right then, right there, that Bard knew they needed caudal anchors because if they stopped caudal migration that the G2 had major problems with and then caused the other failures, they could eliminate failures.

And that's where we get into conscious disregard. Because I want to talk to you about what they didn't tell doctors. They didn't tell doctors, stop using the G2 or the G2X, that we have an anchor filter coming right around. They didn't tell doctors to stop. Use another filter till we give you the safe product.

They consciously disregarded the rights of Lisa Hyde and every patient, including the asymptomatic patients who may be walking out there today, a heartbeat away from death, to protect their market share.

Now, that's a fact. And we saw that. We saw that in

documents and emails and testimony today with Mr. Randall. About how they kept selling it, kept selling it, knowing that the Meridian was right around the corner, but they didn't tell doctors.

And take a look at all the exhibits, but take a look at Exhibit 1940, their own internal analysis of filter failures. Something they didn't tell doctors about. Something they knew and they kept secret, and it was a secret that they did not want anybody to know. They certainly didn't put it in their IFU.

But you ask yourself, by July 2010, are 1,200 MDR, medical device reports, way too many? Are 355 fractures that they're aware of because they got reported, not the asymptomatic, too many? And why are they so far above what the other companies had?

That's not an inherent risk that ordinary people would recognize. That is a company that's hiding a dangerous secret, that is greedy, that wants to keep its market share, and that will make the patients like Lisa Hyde take the risk, the risk they didn't want to take, the risk that would have been too expensive for them.

And they made other choices. They talk about litigation bubble. You know, I don't know what that is. I know what a courtroom is, and I know what a jury is. And I know that's where we get a chance to even things, where a Lisa

Hyde can take on a company like Bard.

And, you know, they had these problems with the G2, the G2X, following the Recovery which was causing catastrophic problems. The G2 was no better. It just went in a different direction, but they kept it on the market. And you saw Janet Hudnall talk about aggressive marketing. That's what won. At Bard, what won was aggressive marketing. Aggressive marketing beat out patient safety, and that's a fact.

And we know that, don't we? Because we know they continued to sell the G2. They even brought it back because they realized they weren't going to get the Meridian out there.

And the real question for you to ask is, what should an Arizona jury -- what should we in Arizona expect of corporations that we have a right to expect corporate citizenship out of?

How about accountability, and if you have a problem and it's dangerous and you have a solution, let the world know, we're working on a solution, but stop. Don't use our dangerous filter.

Now, they talked about Dr. Briant and they talked about Dr. McMeeking, and you can be the judge there. But, you know, Dr. McMeeking came to this courtroom with real solutions, real tests that showed real predictions that we know had been proven out there in the world why these filters fail.

And Bard made a choice. They brought in Dr. Briant.

You know what? Dr. Briant's a very smart guy, and he's a good guy, I think. And he would eagerly jump at the chance to help Bard get to the root cause.

But what they did was they spent $750,000 on Ph.D. engineers just to take and convince you that McMeeking's wrong. Not to come in here with a solution.

And that's because, the evidence has shown, that when they want to talk about a litigation bubble, they made a choice. They made a choice, and they had to live with the choice. Let's keep these dangerous filters out there, and we'll take our chances in court.

Well, that needs to stop right here. Because you just have seen Exhibit 1940, and you know how much worse the Bard filters were and how Bard kept that to themselves. Bard kept a lot to themselves. They kept it from the sales force, they kept that information from the doctors, and if you think about it, every expert that came in here and testified on behalf of Bard -- and that would include Dr. Morris and Dr. Poll and Dr. Briant -- didn't receive the internal documents that talked about the failures that Bard was aware of.

They didn't want them to know because they didn't want them to set them up where they might have to tell us the whole truth and nothing but the truth.

Dr. Muehrcke and Dr. Hurst both had access to those internal documents. We gave them, and just like you, they are

among the few other than people in Bard that have seen the truth. And the truth is, Bard knew that its filters were dangerous in design, and they knew they had to fix it.

They knew they had a caudal migration problem that led to fracture. They knew that the fractures were, their term, Type A and go into people's hearts. That's exactly what happened in this case. And they kept going. Kept going. Kept selling. And they wouldn't stop.

So when you think about a company and what we expect here in Arizona, to put patient safety first, and you think about accountability -- and they want to talk about a litigation bubble.

Well, I think it's about time we talk about Arizona juries. And I think it's about time that we talk about why you're here.

Because you're here because that's -- we need you. We need you to do things that the government can't do, the FDA can't do. They're, you heard, underresourced. We need you because you can sit here and hear the whole truth. You can run, but you can't hide from a jury. And we need juries just like you to find the truth and see everything and see the entire picture.

And to put it as briefly as I can right now, the picture we saw was Bard excited about the retrievable market, but used a permanent device to get on there, and then marketed

every device as a permanent device. Every patient had a reasonable expectation and every doctor had a reasonable expectation that that filter would remain in their body for the lifetime, if that was the choice, and not move.

And Bard knew and kept it to themselves that there was no way they were ever going to meet those patients' expectations. And so that's what this case has come down to.

And the best timeline is in that timeline when they were talking about the caudal anchor right after, right after EVEREST, right during EVEREST, all the way till 2010 and 2011 when the Meridian wasn't available and they went back to their G2. And they continued.

Now, they want to talk about -- I'll call it courtroom math. They know that the incidents and events are underreported, but they use it when it's going to help them. They know that all the filters sold is not the same as all the filters implanted. But they use that because it makes the numbers look smaller.

But they also know, and you heard, that there are how many patients -- nobody will ever know -- that are out there walking around with a failed Bard filter that have no idea.

THE COURT: Mr. O'Connor, you asked me to prompt you at 10 minutes.

MR. O'CONNOR: And they had the opportunity to stop it, contact their doctors, get those patients back, and they

didn't do it.

The reasonable alternative design was there all along. They had it. They knew it. They knew that they had a dangerous design, but they kept the dangerous design out there in the market.

So what I think that we would like you to do is to look at the verdict form and let this company know that here in Arizona, this has to stop. What you decide on here in this courtroom is going to affect countless people in -- it may affect people who are out there now.

It's going to -- it has to be a message to Bard that in Arizona, we expect good corporate citizenship. And that means if you're going to suggest and pretend like you put patient safety first, we're going to hold you accountable for it.

And that means when you know that your filter or your device is dangerous, stop. Don't continue to put the Lisa Hyde of the world at risk of harm.

So as you go through this, we're going to ask you to answer 1 and 2, yes. And then down under compensatory damages, Mr. Lopez talked to you about that.

And then when you get to punitive damages, remember the evidence all the way through. Look at what they knew back in July 2010. And that's Exhibit 1940. And look at what Bard also knew and came in here and admitted. They almost mocked

the people that are out there asymptomatic. And think about the Lisa Hydes out there who may be a heartbeat away from death.

And why should this company take the chance that somehow they may be able to fool a jury when it's in their hands all along to prevent the harm. But they didn't.

And this is a case where you can make it stop by the verdict that you deliver and the message you send, not to the lawyers here, but a message that's big enough that gets to the boardroom at Bard. So they hear you from Arizona loud and clear, and that perhaps this verdict will prevent a Lisa Hyde from happening down the road or in the future. Perhaps this verdict may get them to contact doctors, tell the doctors to get their patients back in, and start screening these patients for failed filters.

I want to thank you for your time. I had to rush through this. But we don't believe in a litigation bubble. This is the jury system, and you are a hardworking jury, and we trust you and know you will do the right thing.

And on behalf of myself and my team, I want to thank you.

THE COURT: All right. Thanks, Mr. O'Connor.

All right, ladies and gentlemen. Just a couple of matters. I mentioned that there are going to be two bailiffs who can work with you in the courtroom. They will be two

people you already know, Traci and Nancy.

If you would each come forward and please raise your right hands.

(Bailiffs sworn.)

THE COURT: All right. Ladies and gentlemen, it's 4:36. We're going to have you go to the jury room. You can take your notebooks with you.

What you choose to do today is up to you. If you want to break for the day and go home and come back and start in the morning, that's fine. If you want to spend a few minutes to pick a foreperson and to start talking, that's up to you as well.

You just decide on what you want to do. If you're going to leave, they will tell you how to contact us with a phone call to let us know you're leaving and when you're going to be back in the morning.

We will be sending back to the jury room with you the jury instructions. The electronic exhibits will be there. We'll send back paper exhibits.

Is there anything else we need to address before we excuse the jury?

MR. ROGERS: Nothing from the defendant, Your Honor.

MR. LOPEZ: Nothing from the plaintiffs, Your Honor.

THE COURT: All right. You may retire. Thank you.

(Jury not present.)

THE COURT: All right, counsel. We'll let you know what we hear from the jury. If you could be sure, if you step away from the courtroom, to leave contact information with Traci so we'll be able to stay in touch with you.

And if they leave, I'm not going to have them come back in here. We'll just let them leave. We'll tell you when they say they're going to be back in the morning so you know when to be back around the courtroom. And otherwise, we'll let you know when we hear anything from the jury.

Thanks.

MR. ROGERS: Thank you, Your Honor.

MR. LOPEZ: Thank you, Your Honor.

Do we still -- we have a CMC tomorrow, did I hear?

THE COURT: Yes.

MR. LOPEZ: 11:00 o'clock; right?

THE COURT: 11:00 o'clock. We'll talk about the schedule for the last two bellwethers.

(Proceedings adjourned at 4:37 p.m.)

C E R T I F I C A T E

I, JENNIFER A. PANCRATZ, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control.

DATED at Phoenix, Arizona, this 4th day of October, 2018.

s/Jennifer A. Pancratz
Jennifer A. Pancratz, RMR, CRR, FCRR, CRC